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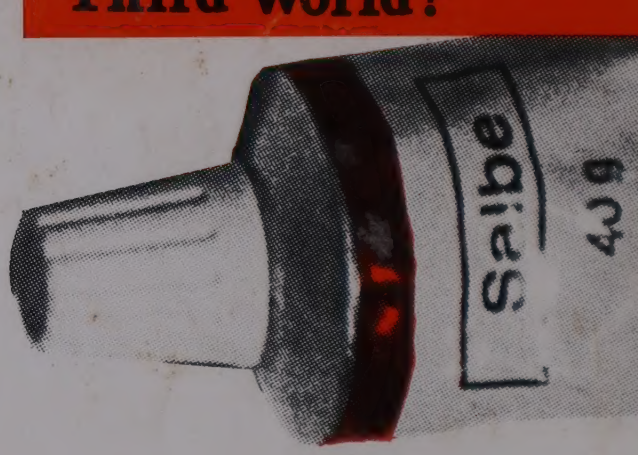
Fewer drugs - Better therapy

Learning from the Third World?



Conference proceedings

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Foreword

On the 16-18th October 1987 the Pharma-Campaign of the Federal Congress of Development Action Groups organized an international Conference on "Fewer Drugs – Better Therapy. Learning from the Third World?". With this documentation the Pharma-Campaign publishes contributions, results, an evaluation of the Conference and some press commentaries on the Conference. We are pleased to present this collection of texts giving a comprehensive survey of the Conference.

We should like to thank once again all those who contributed to the success of this Conference. Special mention must go to the speakers, the interpreters, the numerous helpers, the staff of the comprehensive school Schildesche who had to work at the weekend because of our Conference, and to Barnim Raspe who helped us for several months with the preparation of this Conference. Special thanks are due to Wilbert Bannenberg from Amsterdam for his scientific advice and organizational support.

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International Conference in Bielefeld (FRG) 16.-18.10.1987

Fewer Drugs, Better Therapy

Learning from the Third World?

Friday

18.00	Registration, Dinner
	The present chaos
20.00	**The situation in industrialized countries**; Hermann Schulte-Sasse, Institute for clinical pharmacology, Bremen, FRG
20.30	**The situation in the Third World**, Dr. Mira Shiva, Voluntary Health Association of India
21.00	Break
21.15	**Less drugs - better treatment**, Charles Medawar, UK
21.45	**Possibilities for the implementation of a rational drug-use-therapy (Positivlisten) in the legal sense**, Burkhard Sträter, lawyer
22.15	End

Saturday

Some positive experiences

9.30	**Standard treatment schemes in general practice** Dr. G. Grant, University of Newcastle, UK
10.00	**How do hospital formularies work?** Joe Collier, St. George's Hospital, University of London, UK
10.30	**Positiv- and Transparenzlisten in the FRG** Gerd Glaeske, Pharmacological Advisory Service, AOK Kreis Mettmann, FRG
11.00	Pause
11.20	**National formulary (Zimbabwe)** Jane Moffatt, ex-member of the Zimbabwean essential drugs list committee, UK
11.50	**The Norwegian need clause: Effects on prescription practices** Dr. G. Gadeholt, University of Oslo, Norway
12.20	**Bangladesh's national drug policy** Dr. Zafrullah Chowdurhy, Gonoshasthaya Kendra, Bangladesh
13.00	Lunch

14.30 **Workshops**

1) **From the passive patient to the active consumer** Gert Monheim, WDR TV, FRG ; Ingrid Schubert, Information Centre for Patients, München, FRG; Prof. Borchert, Consumer Association, FRG; Maria Müßeler, Patient

2) **Assistance for the general practitioner: Treatment schedules and sources of information** Dr. Gerd Glaeske, AOK Kreis Mettmann, FRG; Dr. George Grant, UK; Dr. Gunther Hildisch, FRG; Dr. Marc Bouniton, Projet Archimède, Belgium; Dr. Wolfgang Becker-Brüser, arznei-telegramm, FRG; Luc Blondeel, Projekt Farmaka, Belgium

3) **Working with hospital formularies** Dr. Joe Collier, St. George's Hospital, University of London, UK; Dr. Andrew Herxheimer, UK; Hermann Schulte-Sasse, Institute for clinical pharmacology Bremen, FRG

4) **National drug policies: What has to be changed?** Prof. Georges Peters, University of Lausanne, Switzerland; Prof. Schönhöfer, Bremen, FRG; Dr. Wilhelm Schräder, IGES, FRG; David Lee, Huddinge University Hospital, Sweden; Dr. Lewandowski, Ciba-Geigy

5) **The international drug market** Gerardo P. Andamo, HAIN, Philippines; Dr. Zafrullah Chowdurhy, Gonoshasthahya Kendra, Bangladesh; Dr. Mira Shiva, VHAI, India; Dr. Granitza, Schering AG, FRG; Prof. Reich, ZERP, FRG; Dr. K. Balasubramaniam, Health Action International, (Malaysia)

16.00 Break

16.15 **Workshops (continued)**

18.30 Dinner

20.00 Social programme with Tropicaina (Salsa) and videos

Sunday

9.30 **A rational drug policy for Europe from the industrial point of view**, Dr. Lewandowski, Ciba Geigy, Switzerland

10.00 **The rational use of drugs - a universal concept** Dr. K. Balasubramaniam, Health Action International (Malaysia)

10.30 Break

11.00 **How can we implement a rational drug policy?**

Panel discussion with Dr. Balasubramaniam, Prof. Borchert, Dr. Herxheimer, Dr. Grant, Dr. Lewandowski, Dr. Mira Shiva, Prof. Schönhöfer
Moderator: Charles Medawar

13.00 End of the conference

Better therapy with fewer drugs:
Conference produces promising results

The conference on „Fewer Drugs – Better Therapy", held on 16-18th October 1987 and organized by the Pharma Campaign of the Federal Congress of Development Action Groups (BUKO) met with the approval of most participants. More than 240 doctors, pharmacists, health workers, consumers, patients, members of Third World Groups and representatives of the pharmaceutical industry met in Bielefeld with the aim to have a lively and controversial discussion about new ways to a rational drug therapy.

The most important result of the conference: A scientifically justified selection of drugs is therapeutically useful and feasible, and it serves patients as well as doctors. Proposals for different fields were developed and two working groups were spontaneously established with the aim to produce drug formularies for general practitioners and for hospitals.

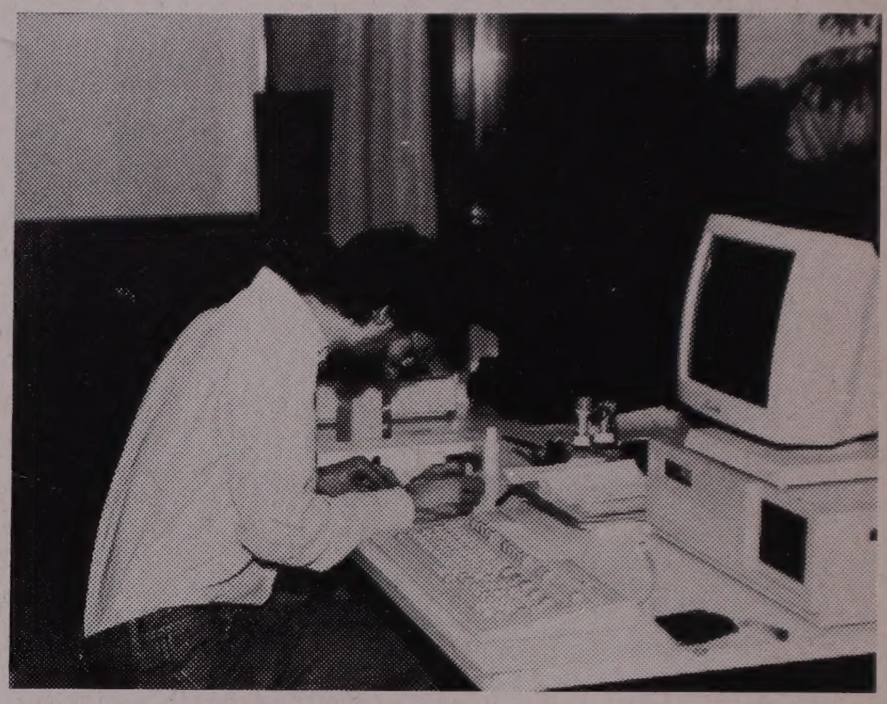
There was a friendly and relaxed atmosphere at Martin Niemöller comprehensive school in Bielefeld. Most participants had arrived on time and everybody had enough things to talk about. Everywhere there were small groups having a lively conversation and waiting for the technical equipment to arrive. The conference finally started 1 1/2 hour later than originally planned.

The present chaos

At the beginning of the conference the present situation was reviewed. Talking about the situation in the Federal Republic of Germany Hermann Schulte-Sasse, representative of the Institute of Clinical Pharmacology in Bremen (and a member of the Pharma-Campaign for many years) reported on the extend of the drug chaos in this country. Even if we do not consider the drugs produced by pharmacies and drugstores, or homoeopathic preparations there are still 47.000 manufactured drugs left (including different formulations). This is definitely more than in other industrialized countries. Norway, for example, has less than 2.000 drugs. Theoretically this drug chaos does not only harm the patients. The „transparency lists" produced on a legal basis evaluated 47% of all drugs in 10 fields of application with the category: „Uncertain and disputed efficacy". Several studies prove that even the most willing doctor must be puzzled. Depending on the different groups of doctors or patients taking part in the studies 30 – 60% of all prescriptions did not comply with a rational therapy.

Rough reflection?

Then Mira Shiva, representative of the Voluntary Health Association of India, reported on the situation in her country and it became obvious that many parallels could be drawn between industrialized countries and developingt countries. Very often the situation is a rough reflection of our problems. However, the consequences of an expensive treatment are completely different. In our countries it primarily leads to higher contributions to the health care scheme wheras in India an inappropriate or too expensive prescription is often the difference between life and death. At the same time „western medicine" penetrates much faster into the country than the „western medical knowledge" belonging to it. Misinformation, unreasonably extended fields of application, the lack of information about risks and the sale of different drugs than in the manufacturing countries also contribute to an irrational drug therapy.



Less is better

Referring to the motto of the conference Charles Medawar described the slogan „Fewer Drugs – Better Therapy" as an antidote against the superstition that more drugs mean better health. The difference between 60.000 drugs in India and 2.000 in Norway speaks for itself. Mr. Medawar pointed out that the overall structure of the drug market needs to undergo a change. A restricted number of drugs will also have an impact on prescribing habits. The doctor will have a better knowledge of drugs he prescribes and of the risks involved. Mr. Medawar went on to say that the sacred cow of research would have to be slaughtered. „Consumers are only interested in real medical progress; everything else must be stopped." Charles Medawar was of the opinion that consumers would be willing to accept useful research and nothing else.

Positive experiences

Burkhard Sträter, a lawyer, referred to the legal aspects of the discussion and he stressed that a rational therapy would be legally enforceable.

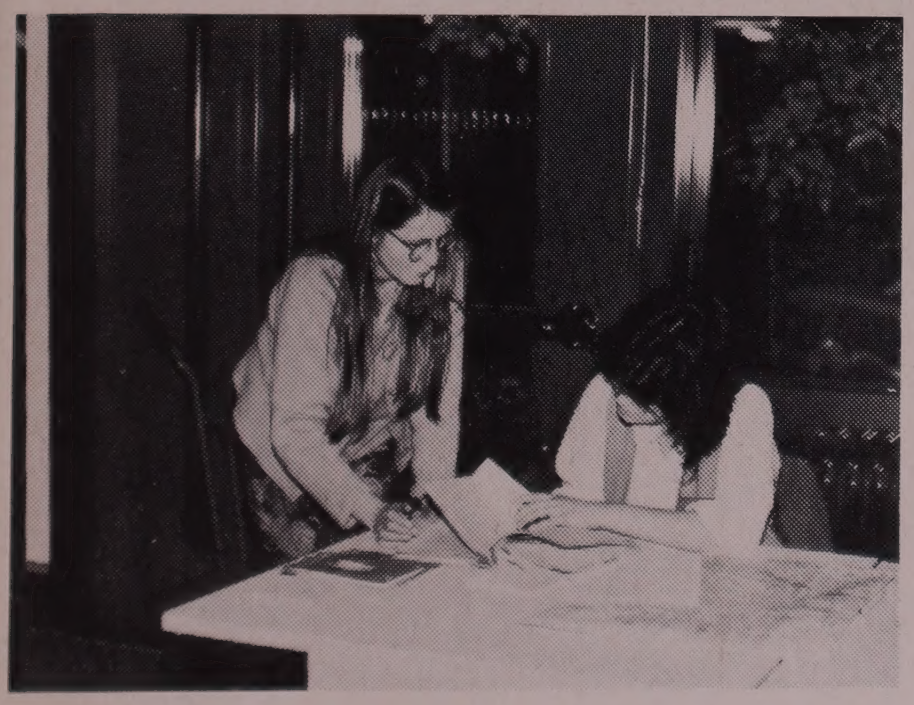
67-year-old George Grant was certainly the audience's favourite of the day. In a charming way he talked about his experiences with standard treatment schemes in general practice. In collaboration with 20 colleagues a team of three general practitioners, who also teach at the university, developed over a period of three years a formulary containing 150 preparations. This formulary covers 90% of conditions which require treatment with drugs. The development of the formulary also benefited from positive experiences that one member of the team had gained with a standard treatment list used in Papua New Guinea. At the end of the presentation participants crowded round Mr. Grand to order no less than 90 copies of his model formulary.

Mr. Grant was follwed by Joe Collier from St. George's Hospital at the University of London who talked about similar formularies used in hospitals. In this field lists are much more common and in many places they have a clear impact on the therapy.

Gerd Glaeske representing the Pharmacological Advisory Service of the Local Health Insurance (AOK) in Mettmann tried to shed a new light on the list chaos in the Federal Republic of Germany. Even though there have been some promising attempts in this respect there are some lists of little value and there are others which are difficult to obtain.. The „transparency lists", for example, are published in the Bundesanzeiger (Federal Gazette) which is certainly not read every day by doctors or patients. The Federal Minister of Finance is not prepared to make more funds available for the distribution of the lists. All the existing lists, however, are insufficient because there is no clear positive selection and this is why the demand for a „positive list" with clear guidelines on the right treatment continues to be an important part of a rational drug policy.

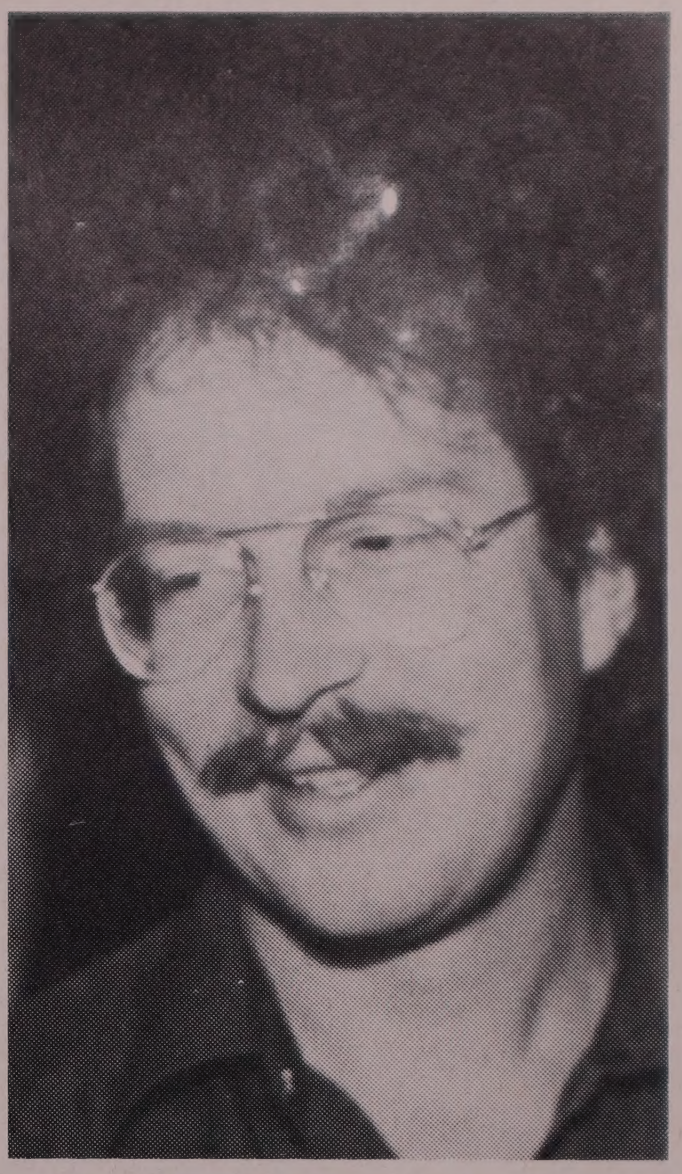
Dr. Gadeholt from the University of Oslo stressed that the major step towards a rational treatment can already be made at the stage of approval. Applying a „need clause" Norway approves drugs only if there is a medical need for them. There are only about 700 active substances on the market. Mr. Gadeholt went on to say that this was sufficient for a good drug treatment and that in spite of the limited quantity some irrational or non-essential drugs were still available.

Zafrullah Chowdurhy from Gonoshasthaya Kendra in Bangladesh reported on how his country succeeded in implementing an integrated drug policy under difficult conditions and which resistance had to be overcome. The supply with essential drugs has enormously improved, local productions has increased and there are fewer problems with regard to quality.



Learning from each other

The five workshops met for one afternoon to discuss better drug treatment in their respective fields. Topics were ranging from the level of the consumer to the political level. The result of the different workshops are summarized on page



Consumer protection

The consumer workshop „From the passive patient to the active consumer" centred around the discussion about consumer rights and the protection of patients from the present flood of drugs. The participants called for the establishment of the position if a „Federal Commissioner for the Protection of Patient" who should represent the interests of patients suffering from detrimental effects of drugs and they called for the reversal of burden of proof from the victim to the manufacturer.

The doctor who prescribes a drug must always inform his patient of the benefits, the risks and of a necessary change of habits. This should be laid down as a right of patients and a duty of doctors.

Consumers call for a transparent and restrictive drug market. Since every patient has a right to receive the best treatment, drugs should be approved only if they offer a therapeutic advance. There was also a demand for the participations of patients in the overall approval procedure, and for the expulsion of representatives of industry.

Helpless doctors?

Most general practitioners are helplessly trying to find their way in the drug jungle. According to the participants in the workshop „Assistance to the general practitioner" 'negative lists' are hardly any help. It would be better to remove drugs with a negative evaluation from the market. On the other hand, positive lists, and in particular those giving recommendations for treatment, can be a big help.

The workshop was very critical of „clinical freedom" that is often used by industry as an argument against any restrictions. The participants said that „clinical freedom" was unacceptable if it implied the „freedom" of a doctor to use any drug without having justify the benefits and risks of the treatment. By contrast, positive lists facilitate the selection of tested and efficient drugs.

However, it also became apparent that positive lists must not be seen as a substitute for other indispensible measures on the drug market, such as the removal of hazardous and non-essential drugs. Furthermore, there was a demand for more independent drug information and an ban on drug promotion.

The workshop set up an initiative which is to produce a European positive list for general practitioners.

Hospitals

The workshop agreed immediately that there should be no hospital without a restricted drug formulary. It is important to involve doctors in the development of such lists and to make the decisions public.

In addition to the lists the workshop discussed several other measures that can contribute to a rational treatment. The participants were of the opinion that doctors should use generic names instead of brand names in their discharge letters in order to improve transparency and to reduce costs. Representatives of the pharmaceutical industry should only direct themselves to the management of the hospital pharmacy and samples should no longer be accepted.

National Drug Policy

The workshop an „National Drug Policy" dealt primarily with the situation i ı West Germany. There are special problems because of „special therapies" (e.g. homoeopathy) which cannot be uniformly regulated by law. (Nevertheless some things need to be changed.) The high number of approvals of drugs every year, which contrasts sharply with the actual benefit, requires stricter approval procedures. Drug information must also be regulated. The obvious disproportion between independent and biased information prevents a rational treatment. In the workshop it was reported that in Sweden 100times more money is spent on biased information than on independant information. In Germany the situation might be even worse. Thus, the right to freedom of information becomes a farce.

International Pharmaceutical Market

This workshop had an extremely controversial discussion. Represantatives of the pharmaceutical industry had some reservations about a restricted drug market because this would prevent innovation and competition. This was contradicted by experiences gained in Sri Lanka and in Bangladesh where a restricted drug policy resulted in a much cheaper and better supply with essential drugs. There was also the opinion that problems might arise with regard to the introduction of new drugs for it is almost impossible for Third World countries to control side-effects which had not been recognized during the approval produce. There was general agreement on the need for international safety standards that should be as high as possible: „Ethic is indivisable."

High Standards?

On Sunday morning a representative of Ciba Geigy had the opportunity to report on „A rational drug policy from the industries point of view". In his presentation Günther Lewandowski set qualitatively high standards for the marketing of drugs, a demand that had not yet been heard from the pharmaceutical industry. This is why the audience called upon industry to keep this promise.

Dr. Balasubramaniam from the International Organization of Consumers Unions was the last speaker. In his presentation he talked about „The rational use of drugs – a universal concept" and he succeeded in mentioning again the most important aspects at the end ot the conference. Dr. Balasubramaniam's speech can be read on page

Many things remain to be done

The most important result of the conference: A scientifically justified selection of drugs is therapeutically useful and feasible, and it serves patients as well as doctors. Even though a restricted drug market can only be gradually implemented many steps toward a rational treatment can be easily realized. If doctors and hospitals concentrate on lists and if they inform their patients of the advantages of these lists we will make an important step toward a better health care system.

We do not want to withhold Charles Medawar's concluding remarks from the reader: „If someone is ill in Great Britain people say 'poor thing'. One thing has become clear during the conference, its firstly that people, who are ill, are not 'things' but human beings and secondly, that if they are poor it is primarily due to the fact that they weak because their natural strength has been reduced or even actively been hindered. One message of this conference is certainly: 'patients first'. Theoretically, this is a clear conclusion which cannot be ignored by a democratic government that feels responsible for the health if its population or by industry which can justify its existence only of it makes a contribution to health. It goes without saying that this goal must be vehemently pursued by consumers."

Hermann Schulte-Sasse

The present chaos: The situation in industrialized countries

Ladies and gentlemen,

the organisers of this conference – and I am one of them – believe that therapeutical options could be better used by limiting the number of drugs available on the drug market – „Fewer Drugs – Better Therapy". In the following, I would like to illustrate that the current situation on the drug markets in the industrialised countries prevent optimum therapy. Since I gained my job experience in the Federal Republic of Germany, most of my examples will refer to this country. The problems are, however, basically the same in other industrialised countries, as the literature on this topic shows.

In a booklet, published one year ago by an ex-president of the **Bundesgesundheitsamt** (Federal Health Authority) – with the Drug Admission and Control Authority being part of it – and by a scientist still active in the Federal Health Authority, the authors with a deep sigh lament the situation on the German drug market: „Nobody knows or can give any information on how many drugs are on the market in the Federal Republic of Germany, and thus available for over-the-counter sales or on prescreiption. This is a crazy, an almost unbelievable situation at a time when everything and each is belived to be registered and stored on mysterious data carriers."[1]

The Federal Health Authority gives a figure of about 140 000 drugs on the market, half of them from industrial production, the other half from the laboratories of pharmacies (approx. 40 000) and from drugstore and health food shop production (approx. 30 000). Among the 70 000 -odd drugs from industrial production, there are about 23 000 homeopathic preparations.[2] This leaves us approx. 47 000 drugs with biological or synthetic active ingredients. Compared with other countries, this figure seems to be surprisingly high. But there are certain snags in such a comparison because drugs are differently defined and counted in different countries. These 47 000 drugs of biological or synthetic origin include all the different forms of administration and doses of one single product. After analysing these drugs one finds a high number of parallel preparations with identical or only slightly modified ingredients and particularly a high number of combination preparations.[1]

Another way of international comparison is confronting the respective physicians'compendia. Dukes used this method for France, the Federal Republic of Germany, Sweden,the U.K. and the U.S. (Table 1) [3]

This comparison shows that the Rote Liste (the german physicians' compendium) offers almost twice as many active ingredients and the multiple of preparations to doctors than the other lists do in other countries, with the United States being an exception here. Sweden, however, shows strikingly low figures in all three points of comparison.

Jumping to conclusions from these figures would mean that particularly in the Federal Republic of Germany doctors are offered a variety of therapeutical options, thus providing an optimum medical care tailored to every individual patient. For the apologists of clinical freedom, this variety of drugs per se safeguards the quality of medical care. Swedish patients would thus have to make do with a considerably poorer medical care.

In 1986, the journal of the Association of German Internists dedicated a whole issue to the problems of drug therapy. In an introduction to the topic, the pharmacologist H.Herken and the head of the medical department of the university hospital of Tübingen W. Dölle complained: „Drugs are the tools used daily by the doctor and he or she alone bears full responsibility for their administration. This requires that he or she can rely on the quality and safety, i.e. efficacy and harmlessness, stipulated in the **Arzneimittelgesetz** (Medical Preparations Act). Experience particularly during the last few years has shown that this has unfortunately not been the case."[5] It is quite obvious that problems are caused the by circumstances of drug supply on the German market.

Complaints about the therapeutic quality of some of the drugs on the market are all but new. 10 years ago the pharmacologists H.Herken and H. Kewitz voiced their complaints on the inadequate regulations of the new Medical Preparations Act as to the evidence of efficacy in an article published by the **Deutsches Ärzteblatt** (German Medical Journal).[6] Three years later, one of

Table 1: Number of drugs in the pharmacopeias in 1981 (quoted in (4)

Country	Pharmacopeia	Act.Ingr.	Products	Preparations
France	Vidal	1,000	2,300	4,000
F.R.G.	Red List	2,550	8,900	11,150
Sweden	FASS	750	1,600	2,500
U. K.	MIMS	1,100	2,100	3,900
U. S.	PDR	1,200	6,000	12,000

the two authors emphasised: „We do not suffer from a lack of highly-efficient drugs, but we suffer from a variety of many, partly unsafe, substances with doubtful efficacy." His conclusion was unequivocal: „This large number, which bothers us extremly, can only be reduced by separating the wheat from the chaff." [7]

The criteria for that recommended „thinning-out" are, however, all but universally agreed upon, at least as far as their concrete application is concerned. For the F.R.G., the results of the official so-called **Transparenzkommission** (Transparency Commission) offer a reliable basis free from the odour of an arbitrary assessment of individual experts. According to these results, 47% of all drugs assessed in the transparency list up to now are of uncertain or doubtful efficacy. [8] Table 2 shows the results of drug assessments in different areas of indications.

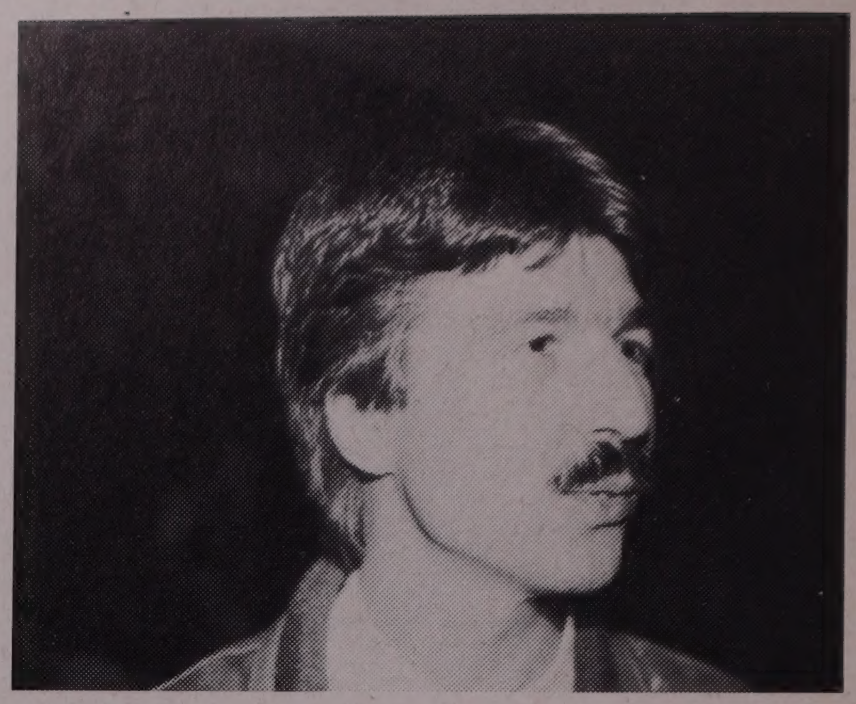


Table 2: Assesment of drugs in transparency lists

Area of indication	Efficacy proven	Efficacy uncertain or disputed	
Angina pectoris	177	222	
Arterial hypertension	502	156	
Arterial peripheral circulatory disturbances	103	181	
Diabetes mellitus	190	87	
Lipometabolic disturbances	83	32	
Gout	163	41	
Myocardial insufficiency	163	220	
Cardiac irregularity	283	57	
Circulatory insufficiency	243	159	
Peripheral venous circulatory disturbances	209	647	
	2,071 (53%)	1,802 (47%)	3,873 (100%)

The decisive question now is: What is the actual significance of drugs criticised because of uncertain or disputed efficacy in medical practice? Are these drugs only peripheral phenomena which are negligible in medical practice? The availability of these drugs says nothing about their significance for the therapeutical behaviour of doctors. „Every doctor committed to a rational therapy (...)," urges the internist K.D. Bock, „will restrict himself to prescribing drugs whose efficacy seems to be certain, and whose risks have been sufficiently tested according to the state of science and knowledge." [9] But—how many doctors are really committed to a rational therapy, or are in a position to act along the lines of that self-commitment? Professor Habermann, the Gießen pharmacologist, pointed out that in many cases belief in drug therapy is much stronger than its foundation. Sarcastically, he added: „In case of need, even experienced drug therapists clutch at a scientific straw, turn hopes into assumptions and these into certainties. They behave like lemmings without water. As soon as the first of them finds whatever so small a puddle, all the others will follow suit." [10]

Habermann's comments make us suspect that the case of a rational drug therapy has not yet gained too much ground. As eraly as in 1962, H. Herken assumed that more than 60% of prescriptions by general practitioners were issued „in credulity of a positive effect" (quoted in 8). The findings of experimental and clinical pharmacology, which have made surprising progress since then, have meanwhile led to a decisive improvement of the scientific basis of drug therapy. This progress could and even should have gained general influence on the therapeutic decisions of doctors. The few analyses carried out on this topic give, however, little cause for optimism. In a study referring to the years of 1974 and 1976, Greiser and Westermann dealt with drug therapy of cardiac insufficiency. According to their results, 60,6% or 55,4% resp. of the relevant prescriptions could not be justified with criteria of a rational drug therapy. In an opinion for the **Bundesverband der Ortskrankenkassen** (Federal Association of Compulsory Health Insurance Bodies), Schönhofer found out in 1977 that drugs with unproven efficacy accounted for 28,3% of the total costs for drugs. (quoted in 8) Within the framework of a pilot study on increasing the transparency of services and costs in the compulsory health insurance system, I analysed the prescriptions of patients who accounted for more than DM 400 of drug therapy costs chargeable to the **Ortskrankenkasse** in the Main-Kinzig-District in the first quarter of 1981. The results showed that 46,1% of prescriptions did not follow the criteria of a rational drug therapy. The majority of prescriptions was on liver remedies and preparations for varicose veins. A group of experts analysed the 50 market leaders for 1981 in the drug index of the Compulsory Health Insurance System. The experts assessed that out of these 50 products, six were irrational combinations and ten were drugs with doubtful efficacy (compared to the range of indications advertised by the manufacturer), i.e. 32% of the 50 drugs which are most frequently prescribed did not totally correspond with the criteria of a rational drug therapy. [11]

The latest Drug Prescription Report '86, published by the Scientific Institute of the **Ortskrankenkassen** also regards the share of rationally not justifiable prescriptions in the overall number of prescriptions to be unacceptably high. „A number of drug groups which are based on still uncertain or disputed therapeutical concepts account for a relatively large share of prescriptions. A particularly high turnover is achieved by preparations stimulating the blood flow, expectorants, external antirheumatic agents, and preparations for varicose veins. In many cases, pharmacological effects have been described only in animal experiments. The evidence of a clinically relevant therapeutic effect was, however, quite often not very convincing." [12]

But not only prescribing unefficent drugs or drugs of uncertain efficacy jeopardises the therapeutic quality of medical care. The diversity of the preparations available on the market will be another threat to the rational basis of clinical freedom, if the individual doctor does not voluntarily restrict himself to prescribing only a certain number of drugs whose action pattern he knows—

for the wanted as well as the unwanted effects. The pilot study started in Dortmund in October 1984 has demonstrated that the number of doctors with a large number of drugs prescribed must not be ignored. Out of the 252 G.P.s. and internists under survey, 17% prescribed between 750 and 1 000 different brands. The authors of the study comment rather cautiously: „An increase in the spectrum of drugs available for doctors to such high numbers induces the question whether a doctor can really be sufficiently informed about the wanted and unwanted effects of so many products prescribed by him. This aspect deserves even more attention since drug manufacturers propose – apart from useful drugs – preparations for prescription which are not that much appropriate for therapy." (13)

In his book „Vom Nutzen und Schaden der Arzneimittel" published in 1977, the late Heidelberg pharmacologist Franz Gross complained about overmedication, which he called a disease of our days. „Expenditure on uneffective or unnecessary preparations swallows up enormous amounts of money which could be better used for the medical care of the population, and additional cost are raised for mending the damage resulting from the inappropriate use of drugs. Thus, overmedication leads to reduced welfare for the people. The prescription of individual products or groups of products which is out of all proportion to the frequency of diseases in which they are indicated, prescribing drugs with doubtful efficacy, administering fanciful combination products are all mistakes of doctors who thus contribute to overmedication. There you have the pharmaceutical industry with its advertising geared to primarily the doctor, which, however, in the case of OTC preparations also addresses the public."

There are, of course, a number of reasons for this lamentable situation which urgently calls for change. The key factors are, however, without any doubt, the insufficient qualitiy standards for the approval and market surveillance of drugs by the relevant state authoritiy, the partly disinforming advertising activities of the drug industry, and the insufficient pharmaco-therapeutic standard of docotrs' knowledge. For the authors of the Dortmund study quoted before, a future change of the German drug market would be a decisive contribution on the path to a better use of the therapeutic potential of the modern scientific medicine. They make the following statement: „The prescription behaviour of G.P.s is influenced by the special features of the German drug market. The extremely high number of admitted ready-made drugs or those treated as if they were admitted as compared to other European countries, the lack of evidence of therapeutic efficacy in many of these products, the extraordinarily large share of combinations which are therapeutically not sensibly composed can act as determinants of medical prescription behaviour, particularly since the information offered by manufacturers is advertising rather than enlightening." (13)

Before concluding, let me briefly mention a particularly unpleasant aspect of pharmaceutical advertising, an aspect which is diametrically opposed to the aims of a rational drug therapy: the existance of „academic salesmen". They often shamelessly use the reputation of their academic title and their university position in order to promote the sales interest of a certain company and a certain product. It is quite surprising how big the number of such auxiliaries is in our country. I could give you a list of examples. A complaint by Graham Dukes shows that this is not exclusively a German problem: „One of the problems has been that industry has become so adept at getting other people, in a position of apparent independence, to promote its views. There are numerous bodies around the world which express views on drugs and which profess independence but which are in fact acting entirely as agents of the pharmaceutical industry." (14) It is necessary to criticize such practices in a more determined and publicity-attracting way in order to stop the disinforming influence of such „scientists" on the prescricption behaviour of doctors.

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Dr. Mira Shiva

The present chaos: The Third World situation

When large percentage of people of any country are deprived of their basic needs to adequate food, safe and adequate water, acceptable living and working conditions, and basic education, a silent crisis already exists. When calamities like floods and droughts hit large number of the already deprived, the crises worsens. When man made disasters by way of debt crises lead to cutting back of essential services, hit some third world countries it is a shame and when exploitation takes place in the name of health it is time to protest.

Large numbers of people in Asia, Africa and Latin America suffer from diseases of poverty. Common along with diseases which of nutritional deprivation are several communicable deseases which are often called, Tropical diseases – which have actually more to do with low resistance to infection because of poor nutritional status and large infectious pool because of poor hygiene and sanitation than with the relationship to the equator for it to be labelled Tropical desease.

The etiology of these deseases lies far beyond the bug/germ which can be seen under the microscope. It lies beyond the organisms growing on the culture plate in the bacteriology lab.

The greatest chaos in our medical world lies in our failure to identify the real causes of ill health. It lies in our incapability and the absence of any desire as well as showing of political will to really do something to change the situation.

It is easy for those having the „voice" and the „power" in the third world countries not to want to identify the real causes.

They find protection from having to make any change by identifying germs und bugs with long names and pathologies, afflicting different organs; having exotic tongue twisting names in medical jargon not merely an attempt to cover up the real causes of ill health is made, but a myth is created that there really exist medical solutions to all ill health and that there is „A pill for every ill".

The policy makers, the producers of the pills, and the major prescribers of these pills, constitute the elite of most of the development, and are over eager to adopt these models, many of which are not necessarily the most appropriate for the third world social context. The people are saddled with imported, costly alienating dysfunctional models of health care.

The National Health Policy document of 1982 acknowledges that „the imported and inappropriate model of health services is top heavy, over centralized heavily curative in its approach, urban and elite oriented, costly and dependency creating."

It is tragic that in countries where indigenous system of medicine eg. Ayurvede, Siddha, Unani existed, and where folk, tribal and herbal medicine were widely practiced and actually have met significantly the health needs of the people, the neglect and marginalization of these indigenous systems has been a great loss. Firstly because it was so closely linked with the culture of the people; it was affordable; easily accessible and non dependency creating on market forces, which have more to do with profits than meeting of the health needs of the people.

The point is not, that all that was done in the name of Traditional Medicine was wonderful and flawless, but the point is that the western and modern medicine that marginalized traditional medicine, was not as scientific, safe and efficacious as made out to be to the third world.

The second major chaos exists in this area of the various existing solutions to ill health, some old some new; some rational some irrational, some dependency creating, some self reliance creating; some costly some cheap; some extensively hazardous, some extremely safe and efficacious. There is a desperate need for education and awareness about rational use of types of health care available.

While several national governments in the third world have opted for the western system of medicine, their people in large numbers still depend upon their country cures, obtained from the local village doctor or(vaid).

„Such myths not merely do they encourage the proliferation of an exploitative drug dependency creating medical system, but they eclipse, marginalize and distort the existing alternatives, and destroy any possible future emergence of meaningful alternative".

Majority of the people are illiterate; ignorant, non English speaking; with little purchasing power; with several being below the poverty line. Western medicine in such a social context leaves scope for misuse and itself becomes a tool for exploitation in the hands of vested interests. Myths about the higher value of a tonic or of an injection over oral medicine of colourful capsule over a pill, the therapeutic value of putting a stethescope on the chest, or painful knee or aching head. The widespread myth, that taking of Xrays has therapeutic value; continues to be created and propogated by vested interest. Health care gets increasingly commercialized and pharmaceuticalized. Since technology for the „medicine making" exists mainly with the northern countries dependency on them increases. To seek medical solutions for diseases for which no solutions exist or for which local, effective and safe alternatives exist. There is no denying that several essential and life saving drugs have a definite role in Health Care – unfortunately the essential, non-essential, irrational hazardous all find a market and no effort to differentiate the good, the useless and the hazardous is made.

Just as ever increasing military industrial complex can not by its very nature ensure PEACE; so also, a rapidly growing Medical

complex guided by profits and not health needs can never contribute anything very significantly to the improved health status of our people. Bigger companies mainly TNCs having greater market control begin to openly or surruptiously change the drug production, drug prescription and drug consumption patterns, Disparities between health needs and drug production pattern continue to widen. This happens often with the known connivance of the third world policy makers or drug control authorities and medical professionals. It also happens due to their ignorance, naivete and implicit trust in the technology and the technogical products and their producers of the west. In several countries national and private companies join in and their functioning often does not differ very much from TNCs. Public sector in some countries tries to fulfil its social obligations by taking on the reponsibility for producing the essential and life saving drugs. Most of the third world nations cannot afford to waste their resources, specially their scarce foreign exchange. In many countries, partly due to the debt crises and partly due to warped priorities the health budgets have been steadily decreasing.

Health budget in successure Five Year Plans

Plan period	Percent share of Health budget
2nd Five Year Plan	3.30
3rd Five Year Plan	2.60
4th Five Year Plan	2.10
5th Five Year Plan	1.40
6th Five Year Plan	1.80

In developed countries upto 5 to 8 % of the GNP is spent on health out of which mere 10-20 % is spent on pharmaceuticals.

In developing countries about 2 % of the GNP is spent on health care of which 50 % is spent on pharmaceuticals leaving very little for other essential health sources. World Bank figures state that developing countries are also spending 5-6 % of the GNP on health care, around 30 % have access to modern medicine. In India 1 % of GNP is spent on health of which 50 % is spent on pharmaceuticals.

84 % health care costs are paid for privately. 80 % of the drugs are available from the private market and not through the government health services 48 % of our people are below poverty line. Only 32 % of our people are literate, only about 2 % know and understand English, the language in which the drug information is given irrespective of the social reality.

Prices of drugs which were already unaffordable are on the way up by 60-300 % following the new drug policy.

According the WHO „Resources are often wasted in purchasing expensive drugs that are only marginally useful or even irrelevant to the solution of a country's health needs where large segments of the population are in urgent need of essential drugs for diseases control and primary health care."

It is a shame when families spend their meagre resources on costly non essential drugs or due to financial constraints are unable to complete their courses.

The drugs are sold for indications not acceptable in the parent countries, with exagerrated claims e.g. Periactin, – Chloramphenicol and to streptomycin – High dose EP drugs, – Anabolic Steriods.

Sponsoring of academic conferences, holiday trips giving gifts and bonuses to promote sales is well known.

Table showing Bonuses given for drugs production which according to the drug companies is higly unprofitable.

Name of Company	*Product*	*Bonus & Incentive offered by Company*
Eskayef	Iodex	Nil
	Furoxone Tab	23+2 Free, Apr 86
	Furoxone Sus	23+2 Free, Apr 86
	Furacin Cream	15+1 Free, Mar 86
	Furacin Powder	15+1 Free, Mar 86
	Furacin Ointment	Nil
	Dependal M tab	23+2 Free
Glaxo Lab	Betnovate M Cream	Nil
	Betnosal Tab	Nil
	Osto-Calcium B_{12}	Nil
Hoechst	Baralgan	Nil
	Novalgin	Nil
	Avil Expectorant	15+1 Free, Dec 85
Parke-Davis	Benadryl Expectorant	37+3 Free Oct, 85
	Chloromycetin	Nil
	Ferradal	Nil
Roussel	Cortasmyl	Nil
	Synastat	Nil
	Soframycin Cream	15+1 Free Apr, 86
Franco-Indian	Dexorange	4% Cash Discount Apr, 86
	Sorbilline	5% Cash Discount Mar, 86
	Cimetidine	5% Through out the year
Cynamid	Ledermycin	5% Cash Discount, Jan 85
	Autrin	Nil
	Myambutol	100+20 Free, Apr 86
John Wyeth	Penidura	Nil
	Wysolone	5% Cash Discount, Feb 86
	Aludrox gol	Nil
Warner Hindustan	Tedral SA	Nil
	Gelusil	24+1 Free, Apr 86
	Waterbury's Compound	8.33% Throughout the year
Ciba	Mexaform	
	Orisul	Could not ascertain
	Otrivin	
Pfizer	Becosules	2% Cash Discount, Mar 86
	Terramycin Cap	Nil
	Terramycin IM Injection	15% Cash Discount, Apr 86
Burroughs Wellcome	Septran	4% Cash Discount, Feb 86
	Actifed	Nil
	Antepar	7% Cash Discount, Apr 86
	Antepar Granules	
Raptakos Brett	Hepatoglobine	940+60 Free Mar 86
	Neogadine Elixir	940+60 Free Apr 86
Unichem	Unienzyme	20+1 free, Feb 86
	E.P. Forte	19+1 Free, Feb 86
	Unicarbazan Fort	20+1 Free Dec
Cipla	Asthalin	
	Ciplin	Could not ascertain
	Ibugesic	
Fairdeal Corporation	Electral	4% Cash Discount, Mar 86
	Vanmycetin drop	24+1 Free Apr 86
	Molzyme	9+1 Free, Dec 85
Dey's Pharmaceuticals	Enterestrep	Nil
	Entromycetin	Nil
	Kombina	9+1 Free Dec 85

There is evidence of the double standards in the drug information given to the third world doctors and probably also the drug control authorities. Third world countries are flooded with uncontrollable number of branded formulations. In absence of well evolved drug regulatory mechanism – several drugs banned in the country find ready markets eg. in India.

1. The following drugs are not promoted by the multinationals in their own countries or in any developed country. Yet they are marketed in our country and have a sizeable market.

Name of Drug	Company	Country of origin	Indications for which they are promoted
Avil Expectorant	Hoechst	FRG	Cough Expectorant
Baralgan	Hoechst	FRG	Anti-spasmodic
Soventol Expectorant	Boehringer Knoll	FRG	Cough Expectorant
Piriton Expectorant	Glaxo	U.K.	Cough Expectorant
Pericatin	MSD (Merind)	U.S.A.	Appetite Stimulant
Osto Calcium B_{12}	Glaxo	U.K.	Growth Tonic
Ganrilon	S.G. Chemicals	Swiss	Pain killer
Suganril	S.G. Chemicals	Swiss	Anti inflammatory
Esgipyrin	S.G. Chemicals	Swiss	Anti inflammatory

Diarrhoea: Over 1.5 million children die in India per year due to dehydration of diarrhoea. Irrational and hazardous anti diarrhoeals continue to be promoted and pushed. ORS which has been acclaimed as the greatest medical revolution of the century is a life saver, if taken in time and in and adequate amounts, while a 1 litre home made ORS would cost 50 paise commercial ORS packs cost anywhere from Rs. 5 to Rs. 8/-mystifying again the very simple solution of diarrhoea. Many mothers known to have thought that it is a medicine to be given directly in the mouth as powder with a few sips of water. Many mothers being very poor and unable to buy 3-4 packets required for severe diarrhoea try to make 1 packet last long enough just as many mothers overdilute baby food supplements to make it last longer. Commercializations of a simple medical concept make the fruits of this medical revolution out of the reach of mothers because of its cost.

Medicines are treated as a commercial commodity by the manufacturers, trade including the government.

Medicines are indicated primarily to yield better „health" and secondarily if at all, any kind of „wealth". According to Dr. Claudia Sepulveda in Development Dialogue 1985 on another development in pharmaceuticals. „To preclude people's accessibility to drug therapy in their moment of need be it directly or indirectly, constitutes a breach of human rights, as health has been unanimously proclaimed a fundamental human right by the governments of the world."

Shortages of essential and life saving drugs

India like many other third world countries does not have an essential drug list. Even those countries that do have a list it is meant only for the extremely small public sector which is constituted of government health services. Even in countries like India which according to Unido, Lisbon conference 1980 belong to category V i.e. capable of self sufficiency – shortages of essential and life saving drugs continue. The fate of the poorest third world countries can be imagined.

While 40.000 children become blind per year in India production figures of Vit A decline. While Johns Hopkins study a correlation between Vit A deficiency and higher infant mortality not merely do we fail to ensure diets which take care of Vit A needs but we even fail to prevent blindness through adequate production and distribution of Vit. A.

S.No.	Name of the Co.	Name of Formulation	Composition	Pack Size	Nos. of the units produced during the year ended December - 1982	1983	1984
1.	M/s Roche Products	Arovit Tabs	Vit'A' 50,000 10 per tab.	8's	22,37,336	21,77,927	21,25,428
2.	-do-	Arovit Drops	1,50,000 10 per amp.	7.5 amp	,20,233	11,195	6,686
3.	-do-	Arovit Inj.	1 lakh 10 per amp.	3 amp	2,67,250	2,35,308	1,79,199
4.	-do-	Arovit Forte	3 lakh 10 per amp.	3 amp	1,93,164	1,46,686	1,42,119
5.	-do-	Rovigon Tab	Each tab. contains: Vit'A'10,000 10 Vit'A' 25 Inj	8's	17,68,533	14,52,019	13,34,547
6.	M/s Glaxo Lab.	Prepaline Caps.	24,000 IV	100's	64,148	42,525	42,965
7.	-do-	Prepaline Inj.		1 ml.	23,790	19,364	4,014
8.	-do-	Prepaline Inj. (Forte)		1 ml.	4,34,651	3,80, 806	28,956

Reply of Minister, Chemicals & Fertilizers, Mr. Veerandra Patil on 14th May in Lok Sabha, Unstarred Question 6371.

Anti-TB drugs

According to the ICMR-ICSSR report we produce only 1/3 of our minimum requirement of anti TB drugs, while India has 1/2 of worlds TB patients i.e. 10 million out of which 2.5 are infectious and 50.000 die annually.

Inadequate Production of anti TB and antileprosy drug and vaccines drug shortages have been reported time and again since in most developing countries it is not made mandatory to ensure production a certain percentage of essential drugs their shortages continue since many of these drugs are meant for those with hardly any purchasing power.

Quality Control

When there are too many drugs and that too in combinations it is not feasible ton ensure quality control. In India we have 60,000 formulations 9,000 pharmaceutical units, 6 quality control labs and around 600 drugs inspectors. Quality control suffers due to failure to ensure Good Manufacturing Practices and its attempts to encourage by buying at lowest tenders without any mechanisms to check the quality control substandard and spurious drugs flood the market.

The trade is more interested in selling those products where higher trade commission and bonuses are obtained.

Chart showing number of MNC substandard drugs

MNCs ALWAYS PRODUCE QUALITY PRODUCTS ?

REALITY

SUBSTANDARD DRUGS

NAME OF THE COMPANIES	COUNTRY	NO. OF SAMPLES FOUND SUBSTANDARD
BAYER	FRG	13
BOOTS	UK	9
BURROUGHS WELLCOME	UK	8
CIBA GEIGY	SWISS	4
E. MERCK	FRG	2
GLAXO	UK	10
HOECHST	FRG	7
MERIND (MSD)	USA	11
PFIZER	USA	9
ROCHE	SWISS	5

Out of a total 218 cases of substandard production of drugs, 135 samples were from 23 multinationals.

Source : UNI Economic Services Vol.III, No.3,5 January '81.

In India every 5th day is substandard, the situation must definately be worse in other developing countries with a less effective drug regulatory mechanism financial and man power resources. While growth and development have meant importing or producing a large plethora of drugs—this growth has somehow not given equal importance to ensuring of effective controls and availability of unbiasied drug information.

Non availability of Unbiased Drug Information

Recent and authentic information is very hard to come by. Most countries do not have national formularies which like the British National formulary could be used as Therapeutic guides. In absence of the availability of costly medical journal and any significant ongoing medical education, the biased medical literature supplied by the drug companies and the comercial guides are the only form that is available to the prescribers for guidance of their prescriptions practice.

Besides specific drug information about individual drugs information about action take by drug regulatory authorities of other countries on some hazardous drugs is not easily available UNCTC's UN consolidated list in that way has been a valuable. Even information regarding banning of certain drugs by the drug control authorities is hardly communicated to the doctors and the chemists effectivets.

Drug Legislations

Most third world countries require their drug legislation, to be made more stringent to be able to prevent unethical marketing practices and ensure prompt action against the violators. At the conferences on Rational Drug use the health activists had pleaded that WHO take on the role of an international supervisory body to ensure that there are no grave violations of ethical marketing practices from one country with effective drug control mechanism to another country in the third world which have undeveloped or poorly functioning drug regulatory mechanisms and weak drug legislation. A role which WHO due to pressure from drug industry was not willing to take up.

SUB-STANDARD & SPURIOUS DRUGS

80% of Indian drugs 'sub-standard'

By A Staff Reporter

BOMBAY, November 1 (Telegraph) ... per cent of the drugs manufactured in the country were either substandard, ... spokesman of the federation of medical and sales representatives' associations ... of India said today.

688 sub-standard drugs sold

BOMBAY Ed., THE TIMES OF INDIA, THURSDAY, MARCH 21, 1985

Drug given to patients was 'sub-standard'

INDIAN EXPRESS, NEW DELHI, 5.2.86

Express News Service

BOMBAY, Feb 4.

Fake drugs getting into Third World

MADRAS THE HINDU, 18 MARCH 85

LONDON, March 17.

Growing quantities of fake and potentially lethal antibiotics are being smuggled into the Third World according to the Observer newspaper

PM's call for two-pronged attack on drug abuse and spurious drugs

THE HINDU, MADRAS 23.2.86

Concern over spurious drugs

DELHI Financial Express, 28.3.86

Our Special Correspondent

Over 10 pc drugs are spurious

DELHI Patriot 15.1.86

Bangalore, Jan 14 (UNI) — Over ten per cent of the drugs being sold in India are spurious according to Indian Medical Association president V Parameshwara

State told to root out fake drugs

23.2.86

The States who ought to ... an ... As against the ... member of ... ... Chief Minister ... New Delhi

States apathetic to spurious drug menace

INDIAN EXPRESS, NEW DELHI, 25.2.86

Express News Service

NEW DELHI, Feb 24.

Drug companies have misused legal loopholes to continue making profits there are several examples in India.

The banned drug case in Kerala High Court 1982 in the Supreme Court 1983. Banning of the EP drugs in 1982. Court cases related to over pricing. Table showing the extent of overpricing and the amounts over charged from consumer is attached.

COURT CASES ON DRUG PRICES AND THE EXTRA GAINS MADE BY DRUG COMPANIES

Name of Company	*Unit*	*Company price/ Units produced*	*Government price/ Sanctioned Units*	*Production*	*Extra Gains in 4 years (Rs. crores)*
HOECHST					
Baralgan Ketone	Kg	24,735.38	1,810.20	12 T	27.15
Glybenclamide	Kg	9,800.00	2,458.20	3.29 T	2.42
P. M. Teracycline	Kg	4,836.00	2,562.00	4.50 T	1.02
GLAXO					
Betamethasone Diphosphate	Kg	2.2 lakh	1.26 lakh		
Betamethasone 17-Valerate	Kg	2.20 lakh	1.06 lakh	2.3 T	21.00
MSD (MERIND)					
Dexamethasone	Kg	1.95 lakh	0.55 lakh	0.54 T	4.90
PFIZER LTD					
Becosules	20s Bot	7.96 lakh without ED	5.58 lakh without ED		
Becosules	100s Bot	29.80 lakh without ED	24.48 lakh without ED		
Becosules Syrup	50ml Bot	4.48 lakh without ED	3.39 lakh without ED		
Multivitaplex Forte Caps	20s Bot	7.80 lakh without ED	5.26 lakh without ED		
Dumasules Caps	20s Bot	7.16 lakh without ED	4.58 lakh without ED		
ABBOTT LABS					
Surbex-T Tabs	25s	9.5 lakh	6.36 lakh		100-150 crores
Surbex-T Tabs	100s	32.88 lakh	22.29 lakh		20 crores turnover
Vidaylin M Syrup	9ml	8.43 lakh	5.81 lakh		
Vidaylin Drops	15ml	5.13 lakh	3.87 lakh		

source : Statement referred to in reply to parts (b) and (e) of Rajya Sabha Starred Question No. 84 for 8 May 1985

Drug Distribution

Drug distribution in remote rural areas is a major problem. Due to poor roads insufficent transport, inadequate storing facilities to maintain the law temperature for keeping of the place. Even if adequate drugs are produced or imported they don't reach the people who need them.

Drug Pricing

Today the sales of medicines is very much in hands of the traders chemists and druggists who have organised themselves to demand higher middle man's cut i.e. the trade commission. The more non essential or irrational the drug is the higher is the trade commission the differencial pricing system in India, makes the production and the sales of the more non essential or irrational drugs much more profitable. The trade is more interested in getting those drugs which give higher trade commission and bonuses than those that meet the health need. In most third world countries private spending on drug is must more than in the public sector. Sales of the drugs from Private sector i.e. the government health services in different countries is given below. Medical care costs all over the world are shooting up. While the purchasing power of the majority of the people is not going up.

R & D

The R & D being undertaken within the country is almost negligible specially if compared to the sales promotion expenses.

The relative shares in dollar value of Pharmaceuticals distributed through the private and public sector services expressed as a percentage of the total pharmaceuticals consumed in 37 Third World countries

Country	Percentage Share in Dollar value	
	Private Sector	Public Sector
1. Argentina	93.7	6.3
2. Pakistan	93.2	6.8
3. Thailand	92.0	8.0
4. Indonesia	91.3	8.7
5. Nepal	90.9	9.1
6. Paraguay	90.0	10.0
7. Phillipines	90.0	10.0
8. Bangladesh	87.7	12.2
9. Singapore	85.0	15.0
10. Belize	83.0	17.0
11. Brazil	80.0	20.0
12. Chile	80.0	20.0
13. India	80.0	20.0
14. Maldives	80.0	20.0
15. Uruguay	80.0	20.0
16. Trinidad and Tobago	78.0	22.0
17. Mexico	77.0	23.0
18. Barbados	76.0	24.0
19. Peru	75.0	25.0
20. Venezuela	74.0	26.0
21. Grenada	72.0	28.0
22. Saint Christopher-Nevis	71.0	29.0
23. Colombia	70.0	30.0
24. Costa Rica	70.0	30.0
25. St. Vincent and the Grenadines	64.0	36.0
26. Jamaica	60.0	40.0
27. Malesia	60.0	40.0
28. Sri Lanke	57.0	43.0
29. Antigua	53.0	47.0
30. Burma	51.6	48.4
31. Bolivia	50.0	50.0
32. Dominica	50.0	50.0
33. Montserrat	47.0	53.0
34. Tansania	45.0	55.0
35. Ethiopia	43.0	57.0
36. Saint Lucia	42.0	58.0
37. Guyana	35.0	65.0

Source: Balasubramaniam K. "The Pharmaceutical Sector in the Third World: A strategy for collective self-reliance" - a paper presented to an International Conference on "Third World: Development or Crisis?" organised by the Consumers' Association of Penang, Malaysia, 9-13 November 1984.

R & D and Marketing by Drug MNCs

A. COMPARISON OF EXPENDITURES ON R & D AND MARKETING BY 52 MNCs

(Rupees in lakhs)

Expenditure Head	*1975-76*		*1976-77*		*1976-77*	
	amount	*% of turnover*	*Amount*	*% of turnover*	*Amount*	*% of turnover*
1 R&D	107	0.3	136	0.4	156	0.4
2 Marketing	1317	3.8	1462	3.7	1534	3.6
Ratio of 2:1		12		11		10

Source : M. Bhagat, Aspects of Drug Industry in India. Centre for Education and Documentation, Bombay 1982.

B. MNCs' EXPENDITURE ON R & D AND OTHER AREAS*

Outlays on R & D	Approximately 0.83% of turnover
Outlays on Sales Promotion and Administrative overheads	Approximately 33.0% of turnover

* Lovraj Kumar Committee Report on MNCs which found that this ratio was unduly high in this sector as compared to other industries

Source : Lovraj Kumar Committee, Ministry of Petroleum & Chemicals 1978

Self Reliance

Several countries are seriously making an attempt towards self reliance. Due to limitations of resources, and technical manpower.

Several countries merely import, finalized products some countries for

mulate. While few others attempt bulk production with as much backward vertical integration as possible with the chemicals industry. While MNC's have been expected to bring in capital and technology to give a thrust to bulk production they have failed in both.

Table showing the Capital braught in initially and the check ward amount resulted to the parent company, is given blow where bulk productions is concerned even through rato for production of bulk, formulations for MNC's was to be 1 : 5 as compared to 1 : 10 by the Indian sector these regulations was openly flaunted. The reward of this flounting of sales and regulations was greater delicensing and decontrol import liberalization and broad banding. Contribution of the FERA (multinationals governed by foreign exchange regulation act) companies as compared to national private, Public and small scale sector can be seen.

It may be recalled that FERA companies i.e. multinational companies were being encouraged to invest and get involved with production of essential drugs.

Several concessions were given to encourage dilution and several comsspanies with 40 % foreign equity shares with total foreign management control started being counted as totally Indian companies. This was very different from other countries where companies foreign eqity share of even 10 or 20 % considered foreign.

Role of MNC's

A look at the nature of the drugs shows which are the major money spinners, a large number of which are produced by the MNC's are non essential.

A look at the production pattern of drugs of some leading MNC's shows that a significant number of their products are non essential and controls a significant of the market of that therapeutic category.

Transfer of Technology & the patents system

Third world countries have bad to struggle to obtain technology or production after paying heavily for it. In countries like India patents are granted for processes and not products and patent period is for 5 years from the date of ceiling of 7 yrs from the date of patents. This is governed by the patent act of 1970 because of which several Indian companies have evolved processes for several essential drugs. Pressure on several government e.g. in Thailand, Malasia, and India is being put to get the National governments to become signetaries to the Paris convention which even according to UNCTAD is not in the interest of Third world countries. By signing the Paris convention countries will be forced to make drastic changes in their own patent acts, at the cost of the growth of their national drug industry and development of new drugs by use of new process and also since patent period would be extended to over 15 years.

Table The role of transnationals in the production of essential drugs in a national priority programme, India.

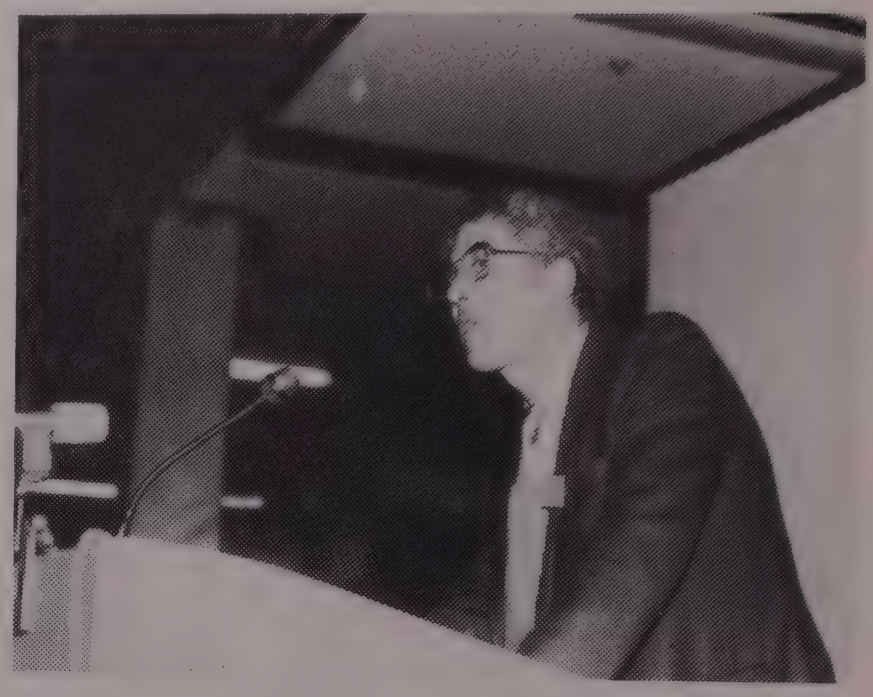
Name of firm	INH	PAS	Thiacitazone	Ethambutol	Rifampicin	Streptomycin
Abbott	Nil	Nil	Nil	Nil	Nil	Nil
ACCI	Nil	Nil	Nil	Nil	Nil	Nil
Hoechst	Nil	Nil	Nil	Nil	Nil	Nil
S.K. & F.	Nil	Nil	Nil	Nil	Nil	Nil
Searle	Nil	Nil	Nil	Nil	Nil	Nil
Sandoz	Nil	Nil	Nil	Nil	Nil	Nil
Roche	Nil	Nil	Nil	Nil	Nil	Nil
Parke-Davis	Nil	Nil	Nil	Nil	Nil	Nil
Sarabhai	*Yes*	Nil	*Yes*	*Yes*	Nil	*Yes*
Boehringer Knoll	Nil	Nil	Nil	Nil	Nil	Nil
Glaxo	Nil	Nil	Nil	Nil	Nil	*Yes*
E. Merck	Nil	Nil	Nil	Nil	Nil	Nil
Ciba-Giegy	Nil	Nil	Nil	Nil	Nil	Nil
Pfizer	*Yes*	*Yes*	*Yes*	Nil	Nil	*Yes*
Warner	*Yes*	Nil	Nil	Nil	Nil	Nil
Burrough Wellcome	Nil	Nil	Nil	Nil	Nil	Nil
German Remedies	Nil	Nil	Nil	Nil	Nil	Nil
Cynamid	Nil	Nil	Nil	*Yes*	Nil	Nil
Ethnor	Nil	Nil	Nil	Nil	Nil	Nil

Source. Majumdar, J.S., 'A Study on Preventive Disease in India',(paper prepared for the drug workshop in Jaipur organised by VHAI), August, 1982.

Charles Medawar

Fewer drugs – better therapy

At the stage of the evening, I should like to be able to tell you a bedtime story but instead I am going to talk briefly about the several meanings of this slogan „Fewer Drugs – Better Therapy". I want to try and explain why I think it is fundamental to rational and economic drug use. The first thing to be said about this slogan „Fewer drugs - better therapy" is that it exists as an antidote to the implicit and very widespread view that more drugs means „more health" and you have already heard and will no doubt hear later during this conference that this proposition is absurd. Logically, it has the intellectual appeal of the suggestion – that we would all be healthier if we ate more, that we would all go faster if we all travelled by car or that we would all be safer if we all carried guns.



Clearly this is nonsense. There is also little or nothing to the logic of the argument that, because we can make progress with new drugs, all new drugs offer some hope of progress. This is fallacious, first because it is quite clear that we can make great progress by using more fairly and also more carefully the drugs that we have; and secondly because there is abundant evidence that most new drugs, most so-called „innovations", in fact offer little or no therapeutic advantage over the drugs we already have.

Because time is short, I will abbreviate the many statistics I could give you, and I want to leave just one idea in your mind to illustrate this. As Mira Shiva has told you, India has 60.000 drug preparations whereas Norway has 2.000. This puts into clear perspective the argument that more drugs means more health. The American consultancy Management Sciences for Health has in fact estimated that as many as 70 % of the drugs on the world market „represent duplicative, me-too, or non-essential products" – many of which are thorougly undesirable, again as Mira has illustrated. In Britain, in my country, a splendid analysis was done by two doctors, two civil servants, of all the new chemical entities, the truly innovative drugs that were introduced in Britain during the 1970s and of these 204 drugs they found very, very few which offered any real therapeutic gain. The conclusion of their study was that „innovation was directed towards commercial returns rather than therapeutic need". That will come as no particular surprise to you but it may surprise you to know that the principal author of this study recently left the Department of Health and is now head of the association of the British pharmaceutical industry. That underlines the authenticity of his report.

However, perhaps the most systematic evalutation there is of the quality of innovation comes from the United States Food and Drug Administration (FDA). The FDA has estimated that some 80 % of all products and 66 % of all „New Chemical entities" offer „little or no therapeutic gain" over the drugs that are already available.

There is another meaning of the slogan „Fewer drugs – better therapy", and that is that the existence of great numbers of drugs implies not only a wasteful and otherwise unwelcome profusion of products, but also the excessive use of drugs: overmedication. And there are two reasons for deploring this: One is that overmedication clearly helps no-one, yet it harms significant numbers of people. In the United Kingdom it is estimated that between 3 and 5 % of all hospital beds are occupied by people who have suffered largely or wholly from adverse drug reactions. For the elderly (who as you know are more susceptible to adverse drug effects) that figure rises to 10 %. One in ten beds is occupied by people largely or wholly because of adverse drug reactions, and excessive prescribing is well recognized as a cause of this. Secondly, the trend to overmedication is associated with over-dependence on the health care system. And that is bad not only for the health of individual consumers – because they abdicate responsibility for their health to the health care system. It is also bad because if you permit there to be such dependence on the health care system, you will bankrupt it. And those two reasons to my mind are the best single illustration of the theme in this conference, „Learning from the Third World". I want to make it clear also that when we talk about too many drugs we are not simply talking about excessive numbers of little tablets or pills, we are talking about the overload of a complete system. What makes a drug work depends on who gets it, when they get it, what dose they get it in, how it is given, for how long – and that in turn depends on the wisdom of the prescriber, what the prescriber knows about the drug, how the prescriber has been trained, how the prescriber has been exposed to promotion and how well the drug has been scrutinized in the drug approval process. So you can see that, if there are fewer drugs on the market, then you are much better able to assess the performance of any new drug against the performance of all other drugs – and that of course is what the prescribing physician needs to know. He or she needs to know about the comparative value of drugs. In Britain right now an enquiry has been set up to study of control of medicines, because the industry is complaining that the drug approval process is too slow. The way to avoid these delays to my mind seems very simple: get rid of the drugs we do not need and concentrate the resources we have on properly scrutinizing the drugs that we do welcome and do need. Similarly, in relation to the training of health care workers, if you have fewer drugs to learn about, you will be better able to learn what you need to know about these drugs to use them properly. The same applies as far as marketing and promotion is concerned and World Health Organization was emphasised in a paper circulated at the 1985 Conference of Experts on the rational use of drugs: „In a saturated or oversaturated market, therapeutic choice is determined by advertising pressure rather than objective evidence." With fewer drugs there is far less need to emphasise meaningless or clinically insignificant distinctions between

drugs. With fewer drugs you reduce the pressure of marketing, and the indirect effect of this is to increase the education of health care providers and indeed of patients.

Obviously, too, if you are using fewer drugs, it is much easier to collect information, in post-marketing surveillance systems, or in adverse drug reaction reporting schemes. It is absurd to be collecting data about drugs we do not need in the first place. Why don't we aggregate larger quantities of data about the drugs we really do need? All of these and other factors have a decisive influence on how drugs work.

When we talk about „Fewer drugs – better Therapy" we are not simply talking about fewer pills, we are talking about improving a complete infrastructure of medicine, and improving overall the management of medicine.

The use of fewer drugs implies something else. It implies not just a wholesale reduction in the number of drugs you use, it implies a higher degree of selection of drugs. I seggest that the use of fewer drugs is a sign of maturity in medicine, because it implies not only that there is selection which is based on an understanding of the properies of drugs, it also implies an appreciation of the priorities that exist, based on an assessment of why you want to use those drugs in the first place. Our present general failure to do this – in particular at national level – is not because we cannot distinguish between more and less useful drugs: it is because of the emphasis which is placed on commercial rather than medical imperatives.

It does seem to me a complete desgrace, that the free enterprise system – which otherwise has a great deal to commend it – should be characterised by drugs in the richer parts of the world by a supply which greatly exceeds demand – whereas in poorer areas, as the World Health Organisation estimated, millions of people die for the want of about $ 10 worth of essential drugs each year.

However, if most member nations of the WHO have reneged on their commitment to „Health for all by the Year 2000", there is at least a good deal of encouraging evidence of rational and economic drug use, mainly from the grassroots. Later in this conference you will hear in particular from Dr Grant about the development of formulary schemes in general practice, and from Dr Joe Collier about the operation of a hospital formulary. Suffice it for me to say at this point that only in the rarest of cases would an individual general practitioner need to use more than perhaps 100 or 200 drugs. Only rarely would a major teaching hospital ever need to use more than a basic list of about 500 drugs, and both of these numbers compare to my mind favourably with the 250-odd drugs that are identified by the WHO as „essential drugs", able to satisfy the vast majority of needs of whole populations.

I want to conclude by dealing very briefly with three of the main objections that are raised to the use of fewer drugs. The first is that by reducing the number of available drugs you restrict choice, and you thereby prevent people from receiving drugs that they really need. I think there are two points to be made here. One is that formulary or restricted prescribing lists are intended simply to cover core prescribing needs, the basic prescribing needs, I do not know of any list and I am sure no such list should exist which totally excludes the prescribing of any other drug. The point is there may be exceptions, but the general rule is for on-list prescribing.

I think it also worth pointing out that the theoretical advantages of being able to choose between many different drugs in order to give the patient exactly the right drug for him or her at exactly the right time cannot in practice ever be realised – if you are talking about more than a few hundred drugs. It is simply quite impossible for an individual physican to know enough about more than a few hundred drugs to be able to prescribe them sensibly. So to have thousands of drugs available makes absolutely no sense at all from the point of view of maximising the advantage of choise for the individual patient.

The second objection that has been raised to the use of limited lists or restricted prescribing or fewer drugs is that we may not realise until a drug has been used for some time advantages which are not obvious about that drug when it is first introduced. The argument here goes that if you stop me-too drugs being introduces you will deny the possibility of useful if accidental drug innovation. I don't think there is a complete solution to this particular problem but neither do I think it an insuperable problem. I would suggest in any case that, you will at least get an indication of the likelihood that that drug is likely to behave in some unexpected way. It might be, for example, that a new member of a class of drugs has a very different half-life from others, or that it uses a different metabolic pathway. Those would be indications that the drug might have properties which would be worth persuing further. But I cannot see this as a substantial objection to limiting the number of drugs to those we really need.

But of course the major reason against the use of fewer drugs is that you will inhibit drug innovation that the industry needs to profit through drug innovation in order to secure future drug innovation. And the short answer to this point, as I have already suggested, that if most innovation is unnecessary or unhelpful you do not need to fund it in the first place. Having said that, I think it should be clear that the consumer movement in its very widest sense is not opposed to drug innovation and can be relied on to support any initiative which will encourage or stimulate useful drug innovation. And I certainly think that the consumer movement would respond sympathetically to any suggestion, for example, of a trade-off which involved allowing fewer drugs being brought to market, but allowing greater rewards for the few that we really wanted and needed. My main point is simply that innovation as such can no longer be regarded as sacred, as sacrosanct. Useful innovation is to be encouraged, indifferent or poor innovation is to be stopped.

By the end of this conference I hope that you will habe been persuaded of thus enough to persuade other people that fewer drugs means wiser medicine, that fewer drugs means fairer medicine and that fewer drugs means better medicine. That is what medicine should aim to provide. Thank You.

Burkhard Sträter

Possibilities for implementation of a rational drug-use-therapy (Positivlisten) in the legal sense

Ladies and Gentlemen,

Let me start by adding something to the remarks made by the speakers before me who talked about the situation of the drug market in the Federal Republic of Germany. The 140,000 fictitiously approved drugs – a figure which was repeatedly taken up during the discussion – must be seen as the result of a very comprehensive and differentiated study of a drug market carried out in 1978 after the new Drug Law came into force. According to this study each individual formulation, each dose, and each generic registration for an unpatented substance must be defined as a drug. When comparing this figure with figures provided by other countries we must first of all find out to what extend the registration systems can be compared. Quite often the figures provided by other countries are based on a count of drug substances rather than on different registrations.

In the Federal Republic of Germany the 140,000 registered drugs contain about 2,500 chemically defined substances (with salts and esters the figure increases to about 6,500) and 900 plants as basic components.

A market analysis of the importance of registered drugs carried out by the Federal Association of the German Pharmaceutical Industry showed that 2,000 drugs already make up 93% of the turnover achieved by pharmacies. The 500 drugs sold best account for 66% and the remaining 1,000 drugs make up 12% of the drug market. I feel that this is quite important for the evaluation of the transparency of the German drug market and that the above-mentioned figure of 140,000 registrations might lead to misconceptions.

Doctors in West Germany can use the following **information media** in order to achieve a rational drug therapy:

The **directions for use** obligatory for new approved drugs in West-Germany give specialized information. Every pharmaceutical company must add these directions for the doctors. One disadvantage of these sources of information and of the comprehensive specialized press is that they normally do not permit any comparative assessment of the drugs available. For this reason three different kinds of drug lists were produced. These lists have a different legal character resulting in a varying degree of obligation for the therapy applied by a doctor.

First of all, there are the **registers** containing almost no comparative assessment. Here, the handy "Rote Liste" must be mentioned.

Then there are the **recommended lists** such as the **transparency list** published by the Bundesgesundheitsamt (Federal Health Office) and the **Preisvergleichsliste (Price Comparison List)** produced by the Kassenärztliche Bundesvereinigung (Federal Association of Panel Doctors), the latter being of special importance as the basis for the examination of the economic efficiency of the therapy applied by a doctor. The transparency list meets high scientific standards but doctors hardly know it because the Federal Ministry for Youth, Family, Women and Health, jointly responsible for the drawing-up of this list, has obviously failed to publish and announce this list in an appropriate way.

Finally, there is the **regulative list** such as the **negative list** which is binding on prescribers. Due to this list certain drugs for so-called "trivial" illnesses are not reimbursed by health insurance funds. Different experiences have been gained with this list in the past. Substitution effects running counter to the aim of cost containment have been noticed.

A **positive list** does not yet exist in West Germany. However, the responsible Federal Ministry of Labour and Social Affairs is discussing the introduction of such a list in the Federal Republic of Germany. It remains to be seen whether it will really enter into force.

As a first conclusion it must be stated that the existing lists are to provide doctors with a guideline, with the exception of the negative list excluding certain preparations from reimbursement.

However, this does not mean that recommended lists have no effect on the therapy of doctors. As so-called anticipatory opinions they have a real impact on the **examinations of the economical prescribing of doctors.** Therefore, I should like to make some short remarks on the inspection system which panel doctors are subjected to in West-Germany. According to the Reich Insurance Code the panel doctor is obliged to prescribe whatever is necessary for treatment. However, he is not allowed to exceed the "limit of what is necessary" and he is not allowed to prescribe drugs at the expense of the health insurance fund. The boards of inspectors of the Kassenärztliche Vereinigungen (Associations of Panel Doctors) examine whether a doctor has abided by the Code by pescribing economically. These boards of inspectors are not restricted to the examination of the individual of drug prescriptions a doctor has issued. In view of the large number of drug prescriptions it would be impossible for them to fulfil this task. According to the Bundessozialgericht (Federal Social Court) they have the right to make a statistical evaluation of the prescribing habits. For each doctor a mean value is determined which is then compared with the corresponding mean values of his specialized group. If the doctor exceeds this value by 50% there is evidence that his therapies have not been economical. If he exceeds it by 20-50% it is assumed that it was necessary for reasons of therapy if it can proved by means of exemplary cases.

If the mean value has been exceeded by 50% exemplary inspections are not required. Legally this implies that the burden of proof has been shifted to the doctor who is now obliged to prove that he did not exceed the value because of uneconomical therapies but because of a special situation in his practice, or he must be able to prove that he can compensate the exceeded value with savings in other fields. If the doctor fails to prove this the boards of inspectors have the right to claim flat-rate damages from the doctor. Sometimes the quantum of damages is extremely high. According to my experiences a retroactive inspection of 8 quarters can amount to a sum of up to DM 100,000. The Kassenärztliche Vereingung sets its claim off against the current fees of a doctor who might not receive any fees for one or two quarters and thus has to pay himself for the drugs prescribed by him. Such a system has quite an impact on the prescribing habits of doctors. In particular, the general preventive effect of such procedures must not be underestimated. Doctors who have been involved in such a procedure can serve as multipliers having a broad effect on colleagues. Every week 2-3 boards meet in the districts of each Kassenärztliche Vereinigung in West Germany with the aim to examine prescribing habits on the basis of the above-mentioned principles.

Doctors promted to treat in an economical and rational way because of this inspecting must automatically use the presently available lists as a quideline. This is also recommended by inspecting doctors of the Kassenärztliche Vereinigung before proceedings are opened.

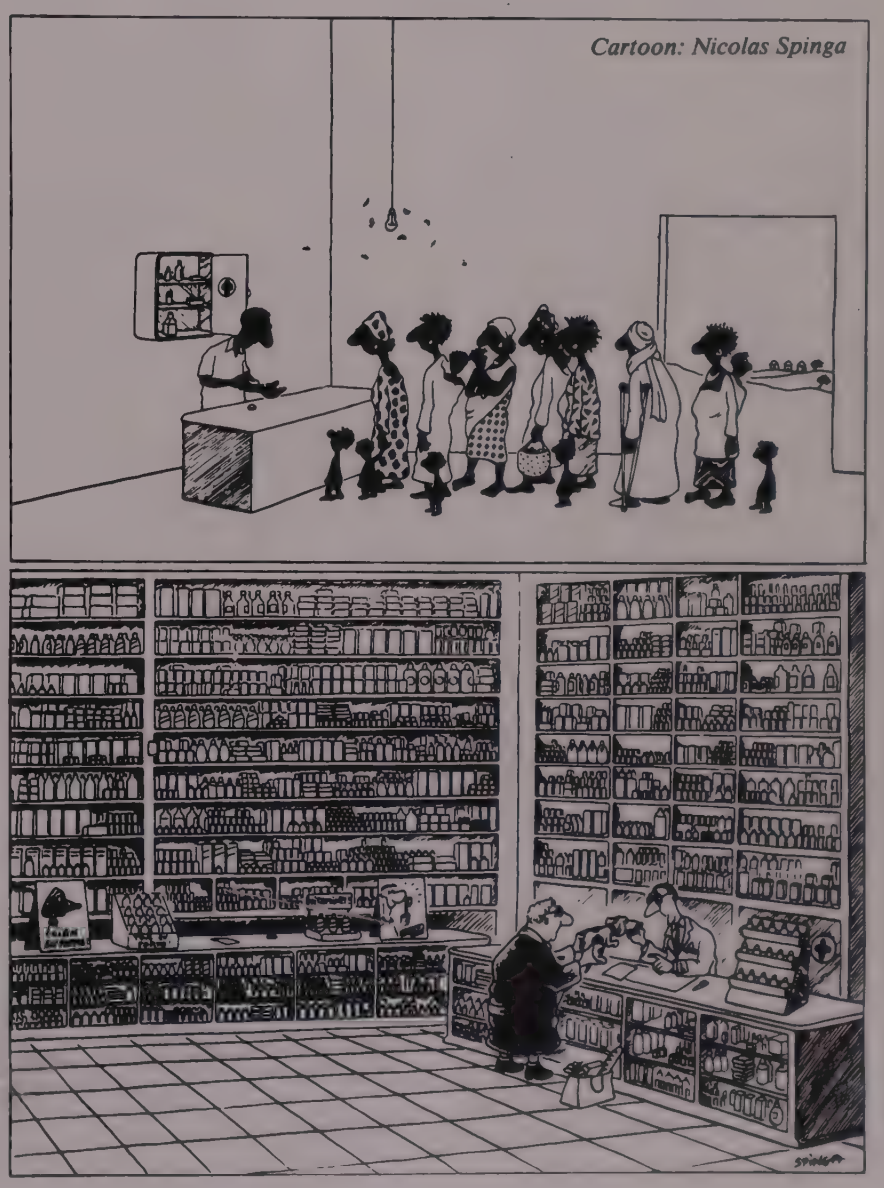
Even though in most cases the present lists are not legally binding they are quite effective within the framework of such examination procedures by prompting doctors to apply more economical and rational therapies.

Obviously doctors are extremely critical of these procedures. Some of the objections to this kind of inspection are certainly justified. I do not want to go deeper into that problem. To my mind, however, it can be concluded that this procedure is effective and that the disadvantages can be eliminated within the framework of the present regulation system.

Therefore, the question arises whether the present inspection system must be tightened by introducing so-called positive lists. Before going into the health aspects of such positive lists I should like to make some remarks on the **legal admissibility of positive lists.**

At present, the legal regulations in the Federal Republic of Germany do not permit the drawing-up of a positve list. The introduction of these lists requires an amendment of the Reich Insurance Code which must be brought about by an amendment of the law. All parties concerned will certainly agree on that point. There is, however, some disagreement on the question whether such an amendment of the Reich Insurance Code is in conformity with the Basic Law of the Federal Republic of Germany. One main objection is that this would be an interference in the established and practised business trade and would thus violate Article 14 of the Basic Law. Furthermore, it is claimed that clinical freedom of the doctor protectet by Article 2 of the Basic Law is violated. I do not want to go into any detail with regard to the present state of discussions. I am in agreement with the prevailing opinion that there are no grave constitutional objections to the positive list as a control instrument for cost containment. According to the Federal Constitutional Court every fundamental right to establish and practise a business trade pursuant to Article 14 of the Basic Law is subject to the so-called legal proviso, i.e. laws can put the immanent limits of a fundamental right into concrete form. This applies in particular to the restrictions on individual property rights for the benefit of society. The exercise of the fundamental right is among others concretely limited by the public interest in the maintenance of a German health care service that can still be financed. It is true that positive lists limit the profit expectations of pharmaceutical companies but these mere expectations are not worth being protected, in particular, if they contradict other public interests and if the legislator limits these expectations. This would imply that positive lists introduced as a legal control instrument are likely to stand a constitutional review by the Federal Constitutional Court.

A question I am more concerned about is whether drugs of **special therapeutic concepts** will have a chance to survive after the introduction of a positive list. As you know, homoeopathic and anthroposophic drugs are of special importance in West Germany. As a rule, manufacturers of such preparations do not have enough economic potential to maintain big research centres. Medicine used in naturopathy is likely to fail the proof of efficacy if, apart from the requirements of the Drug Law, special evidence of efficacy is needed in order to meet the requirements of a rational therapy.



Cartoon: Nicolas Spinga

Therefore, the decisive question is who decides according to which **criteria** whether a drug will be included in the positive list. Our Basic Law obliges the administration to apply the principle of scientific pluralism. Different scientific approaches are protected by our Basic Law. It cannot be the task of an authority to pass an administrative act declaring a certain scientific theory the obligatory theory in West-Germany. This would be incompatible with Article 5 of the Basic Law guaranteeing the freedom of research and teaching. Therefore, the health aspect of the maintenance of special therapeutic concepts also includes a constitutional element. I dare claim that 90% of the mentioned

drugs will have no chance of being included in the positive list if they are exclusively evaluated according to criteria of classical medicine.

I cannot perceive a benefit of advance for drug therapy in West-Germany if we deprive this product group of its economic basis by excluding it from reimbursement thus denying patients the right to decide for a therapy based on the priciples of homoeopathy, anthroposophy, or naturopathy.

Furthermore, compared with other products these drugs are less expensive and therefor such a measure will not lead to a reduction of costs.

Let me therefore stress again that basically, there are no constitutional objections to the introduction of a positive list as long as the constitutional principles relating to the maintenance of scientific pluralism in West-Germany are guaranteed.

Another question is whether the legislator and the responsible political institutions in West-Germany are interested in such a positive list. To my mind, the legislator exercising its discretion must consider the following **effects on health care.**

I'm afraid that positive lists cannot bring about an effective cost containment. Experiences with negative lists have shown that **substitution effects** appear leading to a shift on the market but not to a reduction of the total number of prescriptions as long as the awareness of prescribers remains unchanged. In the near future, the costly demands on drug tests will lead to a shift on the market at the expense of medium-sized enterprises. Due to their research centres big pharmaceutical companies will have no problems to have their products included in the positive list. The remaining so-called "obsoletics" will be less important on increase in sales of the other products. It will be the medium-sized enterprises which will have to pay for these effects on health care. Furthermore, the therapeutic spectrum and thus the freedom of the patient to choose will be restricted. If we want to accept these disadvantages a positive list is constitutionally admissible. However, politicians responsible for health care and legislators should take it for granted that they openly admit these disadvantages and that they defend them in discussions with drug consumers in West Germany.

Within the framework of such a political discussion completely new coalitions will be formed questioning quite often the arrangement of parties in the political coordinate system of left-wing to right-wing parties. As you certainly all know the ecological party of the "Greens" does not have the reputation of being a conservative party in West-Germany. Yet in particular due to the ecological tendency of its policy it also includes a great number of committed advocates of naturopathy. To my knowledge, the overwhelming majority is of the opinion that chemotherapy is the ultimo ratio compared to naturopathy. A positive list is likely to reverse this principle.

I hope, that there will be enough opportunity for a lively discussion of the problems I have raised.

Dr. George Grant

Standard treatment schemes in general practice

Ladies and Gentlemen

I deem it a great honour and pleasure to be asked to speak to you about Standard Treatment Schemes in General Practice as it is a subject which is of great interest to me. I hope that I will be able to convey some of that interest to you and fire you with some enthusiasm to devise such a scheme for the benefit. I feel, of your work and to your patients.

I am a General Practitioner although quite an elderly one and an Honorary Lecturer in the Department of Family and Community Medicine of the Medical School of Newcastle upon Tyne University in the North-East of England.

During the past three years two colleagues and myself from the Department in which we work have developed a **Basic Formulary For General Practice.** This was only possible with the willing help and collaboration of twenty colleagues from different practices in the Newcastle area all of whom are Clinical Tutors in General Practice.

The three of us also provide clinical teaching in General Practice and lead seminars on consultation, other aspects of General Practice and prescribing.

From the preparation of seminars on prescribing, and almost by accident, protocols for teaching and treatment common conditions seen in General Practice, a formulary was conceived. The pregnancy lasted three years and the baby was finally delivered in June this year.

Another contributory factor to the development of the Formulary was the fact that one of us, Tim van Zwanenberg, worked for several years in Papua New Guinea. In the medical service in that country a book of standard treatments for conditions commonly seen, used, mainly by paramedical personnel.

We set out to prove our concept that 90 % of patients, suffering from 90% of conditions which required treatment with drugs could be treated with a simple list of drugs, possibly as few as 100.

Why is this desirable?

Firstly we believe that it is

Easier
Safer
More rational
Cheaper

to prescribe where possible from a standard schedule of drugs. The prescriber should know more detail about a smaller group of drugs of which he is familiar and of course the

Effects
Side-Effects
Drug interactions
Contraindications

I do not know about other European countries but in the United Kingdom we have a comprehensive formulary, The British National Formulary, which is a mine of information. The pharmaceutical companies produce a monthly publication of all their products called MIMS (Monthly Index of Medical Specialities).

Both of these publications are distributed free to National Health Service Practitioners.

Both of these publications contain thousands of drug preparations most of which are available on prescription.

However, we felt that a simpler, smaller, and more handy formulary would be useful and desirable for the use of General Practitioners and also medical students.

Rational prescribing is also desirable in the U.K. where the number of NHS prescriptions has increased form 289 million to 345 million and the gross cost from £297 million to £1,700 (now said ob be £2000) million in the years 1974-75 to 1985-86 it now presents £30 for every citizen and 0.61% of the Gross National Product. Is also represents 11.3% of the National Health Service expenditure.

Having made the decision to produce a formulary we thought that it was important that it was devised by General Practitioners who were actually doing the prescribing. As I have mentioned previously we enlisted and willingly had the cooperation of, twenty of our GP colleagues. We then drew up a list of nine criteria for the development of the drug list. (See box) You will notice that we do not aim to be totally comprehensive but not only to cover 90% of conditions and patients.

A list of conditions was drawn up which was thougt to cover the majority encountered in general practice. These could either be specific diagnoses such as asthma, symptoms for example vaginal discharge or general categories like skin infections.

Under each condition would be listed:

Appropriate drugs and dosage
Practical notes on diagnosis and prescribing
Cost of the drugs per 100 tablets or 500 ml.

A draft formulary was drawn up, shown to, and fully discussed with our twenty cooperating doctors. This took place a residential weekend in the beautiful English Lake District. This list was modified as a result of the full discussion which took place and contained 102 drugs. The twenty doctors then took the formulary to their practices and used it for two weeks keeping a record

of every patient seen with age, sex, presenting complaint or diagnosis, and drug treatment prescribed. These records were analysed and a further modified draft produced which again was used by the twenty doctors. Incidentally we also had ten control doctors, chosen at random, who did not have access to the formulary. The proportion of patients who presented with conditions covered by the formulary was found to be 61-72% after the first draft and 83% after the second. If patients presenting with conditions which would not usually require a prescription were excluded, (i.e. Antenatal, routine medical examinations and certificates) then nearly 90% (our target figure) was obtained. The control group only achieved 32%.

Two further drafts were produced and the final formulary contained 143 preparations.

We felt that we had now proved that in over 4000 patients in twenty different practices these drugs were sufficient to treat 90% of patients seen in them.

At this stage we showed the formulary to Professor Rawlins, who is Professor of Clinical Pharmacology at our University; he was very encouraging, enthusiastic, and suggested that we had it published, in idea which honestly had not occurred to us nor had we even considered. Eventually it was published by Oxford University Press in June this year. We believe that any general practitioner or group of general practitioners could do as we did with great benefit to themselves and their patients. It is very hard work, it is very educational and very satisfying to those who do so.

There are many other aspects of this work which I could develop if more time was available and perhaps they may be brought up at the workshop session. Perhaps I could make one or two random observations.

Firstly, we are aware that some doctors have reservations about the standards of some of the generic drug manufacturers; these could surely be met by a licensing system.

Secondly, we have been criticised for producing such a basic formulary. But remember that this is what we set out to do and that we allowed complete freedom of prescribing as we only attempted to cover 90% of patients thus allowing for patients' idiosyncracies, less common complaints and doctors' preferences. For example, we did not include twelve beta-blockers when two would probably be sufficient. This was the type of policy we followed right through.

Prescribing general practitioners have heavy pressure put upon them by patients, colleagues and not least by Pharmaceutical Companies to prescribe particular drugs. All sorts of gifts, meals, glossy presentations are used by Pharmaceutical Companies so sell their products of which I am sure you are all aware. We have our own way of dealing with them but in the final analysis a general practitioner must make up his own mind on which drugs he is going to prescribe, if any, in a particular case. To do this he must make himself as fully informed about it from as many sources as possible. We do not need thousands of drug preparations.

We do not claim to be pioneers in setting Standard Treatment Schemes for General Practice but we would ask you to consider drawing up your own scheme or using someone elses for the benefit of yourself, your patients, and whoever is paying for the drugs whether it be patient, insurance agency or government (Tax Payers).

We are always available to give help or advice if you require it.

Thank you for listening.

Criteria for Development of General Practice Formulary

(a) To cover at least 90% of the conditions presenting to a general practitioner.

(b) To provide simple, adequate, and appropriate treatment for at least 90% of patients presenting with these commoner conditions (where prescription of a drug was thought necessary).

(c) To be acceptable and useful to a diverse group of general practitioners from separate practices.

(d) To provide a useful tool for teaching medical students and trainees.

(e) To use only generic names for drugs, except for proprietary combination preparations.

(f) To avoid the inclusion of any drug which has been in use for less than 5 years, unless there is overwhelming evidence of the drug's advantages over older preparations.

(g) To take into account cost of drugs as an important but not paramount factor governing their inclusion.

(h) To be compiled by general practitioners for general practitioners; advice of hospital colleagues would be sought when necessary.

(i) To exclude drugs used only in emergencies (e.g., adrenaline) and those normally initiated by hospital colleagues (e.g. insulin, anticoagulants, cytotoxics).

Reference: Grant G.B., Gregory, D.A., van Zwanenberg T.D. Development of a Limited Formulary for General Practice Lancet 1985: i; 1030-31.

Joe Collier

How a restrictive drug policy works in a group of London Hospitals

There are at least 150 hospitals or hospital groups in the UK that operate restricted drug policies. In some the restriction involves all therapeutic categories, while in others it covers selected groups such as antibiotics or intravenous additives. Policies have developed in response to request both from Government (Ministers and Officers of the Department of Health and Social Security) and from those working within hospitals themselves.

In response to these pressures a Drugs and Therapeutics Committee (DTC) was established in the London District of Wandsworth in 1971. By 1977 the DTC resolved to introduce a restricted drugs policy and in 1980 a list of drugs available for prescription was published as the St. George's Hospital Pharmacopoeia (8th edition); the 9th edition appearing in 1982 and the 10th in 1985. This list succeded a series of pharmacopoeias produced at St. George's Hospital since 1768 of which the 7th edition had been published in 1938.

The pharmacopoeia covers all the categories listed in the Britisch National Formulary (BNF) and so includes everything from specialist drugs, such as anaesthetics and drugs for cancer chemothearpy, to vitamins, simple analgesics and cough remedies. The degree of selection varies from one selection to another; for example it includes most for the drugs listed in the BNF for poisoning or immunisation but less than 10% of the BNF's organic nitrates or bronchodilators.

The list, which applies to all medical staff, is used in the hospitals in Wandsworth where there are just over 500 doctors, 2,200 beds and each year handles 410,000 outpatient appointments. The list has now been adopted by two neighbouring districts (Kingston; Richmond, Twickenham and Roehampton) which together have a similar work load to that of Wandsworth. It has also been used as a basis for developing lists in several other districts.

Drugs and Therapeutics Committee

The mainteance of the list is the responsibility of DTC, and pharmacopoeial matters take up about half of the committee's time. The DTC is responsible to a district Medical Executive Committee (DMEC). Constitutionally it is the DMEC that requires drug usage in Wandersworth to be safe and efficient, and the DTC whaich advises on these matters. This relationsship is central to the proper functioning of the restricted policy.

The DTC has elected, appointed, and ex-officio members who reach unanimous decisions on individual drugs. Each of the district divisions (anaesthetics, laboratory services, medicine, obstetrics, oncology, paediatrics, psychiatry and surgery) elects a member to represent them. Nurses, general practitioners and junior hospital doctors each apoint one representative. The ex-officio members comprise an administrator, two clinical pharmacologists, the district pharmaceutical officer, two senior pharmacists with special clinical responsibility, a pharmacist with responsibility for the pharmacopoeia (half her time is given to pharmacopoeial matters) and the district information pharmacist. The chair is elected by the members of the committee. The full committee meets every two months. There are additional meetings of working groups in between times.

Selection of Drugs

The Department of Health and Social Security (DHSS) requested that the policies introduced by DTCs should be concerned with the selection and evaluation of drugs, and that particular attention should be given to effective and economical drug use, but with patient welfare being seen as of primary importance. In Wandsworth the DTC is concerned only with drugs intended for use for their licensed indications. Drugs used in clinical trails are dealt with by the District Ethical Committee.

Drugs for the 1980 (8th) edition of the pharmacopoeia were initially selected by groups of consultants dealing with drugs in their own fields. Each specialist group was given a list of the drugs prescribed locally in their speciality, together with the drugs recommended in the BNF for the same indication. Guidelines were given: the group should only select drugs of proven efficacy and safety, where ever possible fixed-dose formulations were to be exculded (ie, it is better to prescribe one tablet containing amitriptyline any another perphenazine, than a single tablet containing both). Where there was a chocie of similarly effective drugs no more than two were to be recommended and the selection ot these two was to be based on price.

The selection presented by each group was then scrutinised by the committee and after further discussion with the group the list was finalised. In making its decision the committee sometimes included drugs because of their tradtional use and popularity, rather than because there was published evidence for their efficacy. Several of the products included in this way remain (such as Codis' and Paramol—118).

When the 8th edition was introduced in 1980 consultants could still prescribe drugs not listed in the pharmacopoeia although this privilege entailed some delay because non-listed drugs were not stocked and so would have to be specially ordered in. However the regulations were changed a year later and since 1981 consultants can only prescribe drugs that have been approved by the committee.

Introducing new Drugs

A new drug can be brought in for a named consultant for an appraisal period of up to 6 months (in 1986—87 just over 30 drugs were so appraised). By the end of this period a full request has be lodged with the committee if the drug is to be considered for continued use: about half of appraisal drugs are prusued in this way. Consultants may also make a full request without using the appraisal period and this is the approach used for about 10 applications each year.

To make a full request consultants are asked to give „Evidence that the proposed drug has advantages in terms of safety, efficacy, convenience and/or cost compared with equivalent drugs already listed in the pharmacopoeia. Evidence should rely heavily on well controlled published trials. If the manufacturer of the drug is willing to help to prepare the submission this is acceptable". Details of costing are provided by the Pharmacy Department and in the selection procedure it is the cost to the hospital, rather than the cost when the drug is obtained through the high street chemist, that is the primary concern of the DTC. The

cost to the hospital is usually about 25% lower than for drugs dispensed outside. Occasionally however the price offered to the hospital is an obvious inducement (1/80 the market price) and in these circumstances the issue of cost to the community is considered.

The mechanism for discussing the application for the new drug is based on the Medical Research Council's method for assessing grant applications. Each request is allocated to a member of the committee to read and scrutinise, to check the references, and to discuss particular issues with the applicant or colleagues if necessary. The member then presents the application to the committee, comparing the new drug with those already listed, and assessing whether it has advantages in terms of efficacy, safety, cost or convenience. The application is then discussed until a unanimous recommendation is achieved. Usually a decision can be made, but occasionally the committee will defer judgement until further information is obtained from the applicant. Sometimes the application is for a clinical trial and so is redirected to the ethical committee. If, after discussion, the drug is accepted it can become available either generally (about half of the successful applications), or be restricted to consultant staff only (such as Duovent'[fenetoreol hydrobromide and ipratropium bromide]), to certain specialties (such as isotretinoin capsules to dermatology), or to certain locations (such as trimetaphan camsylate or dopamine to intensive therapy units). A rejected drug is not available in the pharmacy (this affects only 2-3 full applications per year). These decisions are put into effect only after they have been ratified by the DMEC.

For new formulations of pharmacopoeial drugs the procedures are a little different. A list of the recent changes is presented at each DTC meeting and new formulations are discussed in terms of their efficacy, safety, cost, and convenience compared with the drugs already listed. Many of the new forms are accepted without further debate, but if concern is voiced the formulation is treated as a new drug and a consultant's request is required.

Just over 40 new drugs/formulations are added to the pharmacopoeia each year.

Losing drugs is more difficult than might be supposed. Consultation leading to the loss of a drug has to be as detailed as that for its inclusion. Naturally drugs that are no longer manufactured or for which the licence has been withdrawn are dropped from the list. Drugs. not prescribed for a period of 6 months are also considered for omission. Approximately 50 formulations are lost this way each year.

Examples of decisions taken by the DTC are given below:

1) New formulation accepted „on-the-nod"; mefenamic acid dispersible tablets. These were an advance on the capsules which some people find difficult to swallow.

2) New formlation rejected: Slow Release Bezafibrate tablets (400 mg).

3) Consultant requests rejected; megestrol acetate, glyceryl trinitrate patches.

4) Consultant request that went directly to the DTC with no 6-month appraisal period; sodium picosulphate.

5) Consultant request for which the appraisal period was used but which was not followed by an application; pirbuterol.

Adherence to the list

The only outlet for drugs in hospital is through the pharmacy, and cooperation from the pharmaceutical staff ensures that the only dispensing of „non-pharmacopoeia" drugs is for drugs undergoing 6-month appraisal, for those involved in clinical trials and the occasional pre-1981 drug still available on consultant signature. These extra-pharmacopoeia items account for just under 3.0% of the district's total annual drugs budget.

Safety

Although one aim of the limited list is to improve patient safety it is difficult to know whether this is being achieved. Since fewer products are available doctors should be more familiar with the drugs they are using and accordingly should be able to prescribe more rationally and so better avoid unwanted effects. However the only concrete evidence that patients will have been protected comes from the fact that of the sixdrugs recently withdrawn from the UK market because of unacceptable side effects, five (feprazone, 'Osmosin' [controlled-release indomethacin], zimeldine, zomepirac sodium and nomifensine) were never generally available in Wandsworth.

Controlling Costs

Information on drug purchasing is kept on a computer, data being entered as the drugs are distributed to the different hospitals in the district. At each meeting of the DTC figures are provided giving details of the expenditure for each hospital month-by-month, and from time to time the drugs are presented under about twenty headings such as cardiovascular, infections, eyes, skin, etc. From these it is possible to identify trends in costs for periods of up two years and detect changes in costing of the broader areas (such as analgesics, antibiotics). Once areas of high expenditure have been identified details are obtained on the actual drugs used in any special category over a preselected period (usually the previous 3 months). With this information, smaller „User" working parties are convened to analyse trends and assess how changes should be made to reduce costs and possibly to improve compliance with the list. The DTC then considers the party's recommendations. There are also standing „User" groups such as those for family planning clinics or infectious diseas, and they too make recommendations in the same way.

Between March, 1982, and July, 1984, Wandsworth had a relatively stable practice (no hospital closure, no change in bed number of staff) and the same stability has again existed since January

1985. Accordingly for those years it has been possible to compare prices from one year to the next. Each year the national hospital drugs bill is believed to increase by about 10%; in Wandsworth the average annual figure is closer to 4%. With this differential the estimated amount saved between 1981 and the end of 1987 will be almost £ 1.3 m. Savings of this magnitude come not only from selecting the cheaper drugs alternatives, but also because a limited list greatly improves our negotiating position when arranging contracts with manufacturers or suppliers.

Saving, albeit small, also comes from the reduced work load put on the pharmacy and also because throughput of individual items is increased there is less wastage from drug expiry before they can be dispensed.

There may also be savings at a wider level. About 10% of the annual turnover of the drugs industry is spent on promotion. Limitation of this exercises could save hundreds of millions of pounds. In Wandsworth, representatives of drug companies are encouraged to direct themselves towards consultants or members of the drug and therapeutics sub group and they remain quick to inform consultants of possible therapeutic advances.

Problems with the Pharmacopoeia

There are two main problems arising from pharmacopoeia; one is the time and expense needed to run the list effectively and the other is the work needed to ensure adequate communication and maintain good public relations. It is difficult to claculate the exact work load engendered by maintaining a limited list, suffice to say that it requires a pharmacist (plus computer/word processor) working half time on the project, a secretary committed on average for about five hours per week, and the same commitment from the chair of the committee. In addition there is the cost of printing and distributing both the pharmacopoeia and its bimonthly up-dates; updates are produced by the pharmacy after each DMEC meeting, new editions of the whole pharmacopoeia appear approximateley every year to eigtheen months.

The second problem is that of communicating the results of DTC decisions. The applicant is informed personally of the outcome within days of the committee meeting and the minutes of the DMEC are available to senior medical staff. In addition updates and pharmacopoeias are distributed to medical staff, to wards and to outpatient departments. Yet despite these commitments, and its seven years existence, it remains common for pharmacy staff to have to remind prescribers of the contents of the pharmacopoeia and to give details of how the limited list works.

Conclusion

A restricted drugs policy has now been used in the hospitals of the London District of Wandsworth for seven years. The policy has reduced drug costs to the district and helped improve patient welfare. It saves time in the pharmacy which now has to handle fewer drugs and probably improves prescribing by staff who have fewer drugs with which to become familiar. It has also helped improve the welfare of those taking part in drug studies; by a close liason with the District Ethical Committee it has been possible to eliminate the use of drugs for unauthorised (non-approved) studies.

Despite the obvious advantages of a restricted drug policy one should not underestimate the level of commitment required to ensure that the policy is professionally acceptable. To be effective a locally run pharmacopoeia probably needs the resources of a large hospital or of hospitals working in groups.

Dr. Gerd Glaeske

"Positiv- und Transparenzlisten" in the FRG

The intransparancy of the drug market in Germany is clear, the figures speak for themselves: 145,000 different preparations or dosage forms were to be found on the German drug market before 1978 and are regarded as admitted within the framework of the transitory regulations of the valid Medical Preparations Act. A further 5,979 drugs were approved by the Federal Health Authority between 1978 and September 1986 so that the total figure of products available on the drug market amounts to more than 150,000. Looking at the fact that even the number of new admissions – 5,797 – is higher than the total drug market in countries such as Denmark, the U.K., Finland, Iceland, the Netherlands, Norway, Sweden, and Switzerland makes it even the more clear how irrational such a drug market with more than 150,000 drug variations is.

Since the Federal Health Authority is obviously not in a position to raise the threshold of approval thus making the access to the drug market more difficult, but on the contrary rather wants to excel with annual "admission records" – in 1979 only 362, in 1985 already 1,055 – it is not surprising that completely different sectors think about market structuring measures: If the pre-market control with the admission of a drug being the central event does not or only partly work, at least the so-called post-market, i.e. in the field of administering these admitted drugs, should be put in order and made transparent. All this should be done bearing in mind that intransparency can make drug therapy unsafe, qualitatively doubtful and uneconomic.

The higher number of products on the German drug market is certainly partly a consequence of what is calles a „formulation" in the Medical Preparations Act: This term also comprises tea preparations, medicinal mineral waters, preparations belonging to the field of homeopathy an anthroposophy.

But even a restricted view will leave more than 30,000 drugs which can be regarded as a typical resource of prescriptions. And even this figure is higher than the number of drugs in comparable European countries, e.g. within the EEC.

This figure rules out right from the beginning that the doctor will be unable – on the basis of his own knowledge and expertise – to come up to his responsibility of applying the therapeutically most appropriate and at the same time most economic drug out of all the drugs available. Starting out from the assumption that a doctor should be able to evaluate the drugs he wants to apply with the help of his own therapeutic experience and knowledge of the basic literature, the application of more than 500 to 1,000 drugs will simply be impossible. The studies of a "transparency projct" showed that doctors "who prescribe up to 1,000 drugs or different ready-made preparations per quarter, but are only so well informed about 200 of them that further reference to literature is unnecessary, would have to dedicate about one working hour per day to drug information, provided that he needed only six minutes for getting information about every drug exceeding the basic number of 200." (H. Friebel et.al., Pharma Ztg. 1/2, 20, 1987) In this context, the next step inevitably is pointing to formularies in hospitals where a qualitatively safe drug policy is pursued with such a limited number of drugs, or to the List of Essential Drugs by the World Health Organisation with approx. 250 active ingredients.

As long as this discrepancy between the demand of drugs on the one hand and the supply of drugs available on the market on the other hand is accepted, it is essential to provide above all the doctor with a view to his prescription behaviour, but also the consumer or patient with additional information which allows a comparative orientation within the market supply. Such data could also be useful for the health insurance systems as those bearing the costs as well as for the suppliers, i.e. the drug manufacturers, which need data with a view to the marketing possibilities of their products.

Last but not least, it should be in the interest of the admission authority to compare and evaluate the results of its individual decisions in the admission process.

Creating transparancy would thus be "consumption control by information", in which almost all those involved in the market would be interested, even if their degree of interest varies. Attempts to list drugs at least in a comparative way can thus be found with all those involved. Some groups go one step further and publish also comparative evaluations.

1. An exclusive listing of the most common drugs in the Federal Republic of Germany is the "Red List", published under the auspices of the **Bundesverband der pharmazeutischen Industrie** (Federal Association of the Pharmaceutical Industry). The approx. 8,800 drugs in this list are categorised according to groups of indications, and their sizes of packages and prices are given. This list is free for every doctor. Since this list does, however, not provide any assessments nor information on dosage costs per day, and since it does not always give complete, sufficient information on contra-indications, adverse drug reactions, etc., this publication of the Federal Association of the Pharmaceutical Industry is an inappropriate tool of information to achieve transparency on the drug market.

2. The book "Bitter Pills" tried to clear a path through the drug jungle for the consumer. This book contains all drugs which in their range of indications together accounted for 80% of turnover, i.e. that almost all common drugs are listed in this book. The authors tried to be clear and understandable in their assessments, and the ADRs which seemed to be particularly important for the consumer were listed. However, no comparable prices are given.

3. The book "Drug Prescription Manual for Doctors and Students" is published by members of the Drug Commission of the German Medical Profession and contains, listed according to a classification scheme of indications and active ingredients, those drugs which the Commission deems important enough. Whereas in the past editions, e.g. in the 1976 edition, on overview of the total market was given and many drugs were negatively assessed, from the 14th edition onwards only such drugs have been listed which could be considered for a rational drug therapy. This manual by the Drug Commission of the German Medical Profession can thus be regarded as a kind of "positive list", though a rather extensive one. It does, however, give no information on comparative assessment nor on comparative dosage costs per day. What should be mentioned is that the index contains approx. 3,000 brand names or their components, the overall figure of entities being an estimated 400 to 600.

4. The **Transparenz-Telegramm** (Transparancy Telegram) is presumably the most commonly used publication in the drug market, which lists all the important allopathic drugs according to their indication – monopreparations in an almost complete form, combination preparations partly to be supplemented – and gives information on their assessment, based on literature and on the dosage costs per day. It is produced by a private institution with the aim of creating transparancy on the drug market for doctors and for health insurance institutions. If transparancy meant nothing else but product information (active ingredients, ADRs, interactions, etc.), assessment and dosage costs per day, the Transparancy Telegram would be a publication living up to these demands. Criticism is, however, sometimes raised because the assessment are largely based on anglo-saxon literature and because too little practical expertise feeds into the Transparency Telegram. This publication has a circulation of 15 to 18,000 copies in the Federal Republic. Approx. 50% of the 7,000 entries of the recently published new edition got a negative rating.

5. The so-called "Evaluating Drug Index" is also published on the basis of a private scientific initiative as an information for doctors. An expert group consisting of pharmacologists, clinicians and general practitioners rates individual drugs classified according to their indication, and assesses the appropriateness of the preparation for the indication claimed. The methodology used here is closely linked to the Drug Efficacy Study carried out in the United States between 1966 and 1969. Although therapeutical transparancy is achieved by comparative assessments, the important information for the doctor on dosage costs per day for the drugs compared is lacking, and this certainly is one of the most important criteria for the selection of drugs. The result of all volumes of this Index showed that only approx. one third of all drugs under survey are eligible for a rational drug therapy.

6. The **Bundesausschuß der Ärzte und Krankenkassen** (Federal Commission of Doctors and Health Insurance Institutions) works out price comparison lists, based on art. 368 p paragraph 1 section 2 of the German National Insurance Code (RVO), containing all allopathic drugs available according to groups of indications and active substances, as they are listed in the German drug list. It provides the doctor with information on dosage costs per day. The latest edition added group ratings to these prices by placing each preparation – for only a selected range of indications still – into either category A, B, or C. This classification equals the therapeutic use in a descending order. For example, category C lists such preparations which should be prescribed "with particular care" (e.g. senseless combination preparations or obsolete monopreparations). This list is compiled be representatives of the medical profession and of the health insurance institutions and is made available to all doctors working in the Compulsary Health Care System (correspond to NHS doctors).

7. The Transparency Lists of the Transparency Commission of the Federal Health Authority, now regulated in art. 39a ff of the Drug Act, take the demand into account to make the drug market – divided up according to different indications – pharmacologically and therapeutically transparent and to achieve transparency of prices, thus determining the face value of different preparations with the same indication. The Transparency Lists would thus fullfil the basic demands for achieving transparency: Openness and clarity in the criteria of therapeutical efficacy, number of drugs, drug quality and price. They are meant to enable the doctor to compare and evaluate different substances, effects and ready-made preaparations with a view to a certain indication before taking the decision what to prescribe. A number of experts are involved in this evaluating process of the Transparency Commission, who are appointed by the Federal Minister for Youth, Family, Women and Health. Apart from representatives of the medical sciences, of pharmalogy, health insurance institutions and consumers, also drug manufacturers are represented in this body. The drug under discussion is assessed by the Transparency Commission on the basis of clinical test results presented by the maufacturing company. By the end of 1986, ten lists were completed, in only 53% of all drugs included in this transparency analysis efficacy was unequivocally proven, in 47% efficacy was either uncertain or doubtful. This is certainly a result which shows the necessity of demanding transparancy as a precondition of a qualitatively assured and cost-effective drug therapy.

These transparency lists have to overcome two problems: their wording and their way of distribution.

Wording are partly vague and can only be understood when knowing the total list. Therefore it has to be assumed that it is difficult for the prescribing doctor to understand the assessment in the Transparency List at the moment of therapeutic decision. This problem of clarity partly certainly rose from the necessity of taking a balanced decision about the different drugs. Furthermore, individual assessments are the exception in the Transparency Lists. As a rule, drugs are combind to groups of active ingredients and then assessed as a group.

The other weak point is the publication of the Transparency Lists in the **Bundesanzeiger** (Federal Legal Gazette), due to the fact that the Transparency Commission has a public mandate on the basis of legal regulations. This Federal Gazette, which usually publishes newly adopted laws, is certainly not a publication which is routinely read by doctors. Ordering individual Transparency Lists seems to be an extremely cumbersome way of getting this information. It should therefore be considered by the **Krankenkassen** or the Medical Associations to make the Transparency List available to every doctor. It would also be a good idea to write these Transparency Lists in a more user-friendly and understandable way. On the whole, these Transparency Lists follow criteria which can be regarded as preconditions for a rational prescription behaviour. The acceptance of the decisions taken in the Transparency Lists can, furthermore, be rated as high, since all groups involved in the market have participated in the decisions on the different drugs.

Do all these attempts now suffice, which taken as a whole might even create a new intransparency of information? The question

which of the information instruments described above is the most appropriate one for achieving transparency cannot be answered immediately.

Apart from that, none of these lists has had a clear influence on market structures. Like in the past, the drug market in the Federal Republic of Germany to be untidy, fraught with products of doubtful therapeutic efficacy, overloaded with a huge number of newly admitted drugs in combination with a price structure which is unprecedented in Europe. In my eyes, the still existing intransparency of the market helps no-one but the drug manufacturers, since there is only little concentrated resistance towards the marketing strategy for drugs already on the market or for newly admitted drugs – the broad market covers the problems of individual drugs and can hardly be controlled and structured. Restricting lists or, for example, positive lists would be an adequate solution to such an overflowing market and are indispensible with a view to the mandate of cost-effectiveness and a qualitatively safe drug therapy. These positive lists could be drawn up out of the already compiled Transparency Lists without any additional expenditure, and would thus be the framework for prescriptions, at least for drug therapy in the compulsory health insurance system.

Such positive lists which are based on the scientific findings and have to be updated continuously, comprising apart from the criteria for admission – i.e. efficacy, safety and quality – the additional criteria of comparative therapeutic benefit and cost effectiveness, are in my view the only sensible reaction to admission philosophies with a very low access berrier to the market and to an innovation strategy of drug manufacturers which lauch a great number of rather insignificant molecule-variations or even senseless combination preparations as innovations with a comparatively low expenditure. If approx. 90% of the population – this is about the share of those insured in the compulory health insurance system – got prescriptions with drugs from such a positive list, this would have an effect on market structures from the very first day: Only those drugs will maintain their significance on the market which have been adopted into this prescribing list.

Before the adoption into a positive list, not only therapeutic benefit has to be proven, but also the fairness of price – eventually some hope that a genuine competition on the market raises the drug manufacturers out of ther paradisiacal peace!

Up to now, only few social forces have explicitly voiced their demand of a positive list in the Federal Republic. Among them are the trade unions and some **Krankenkassen.** Discussion still focusses on the disapproving attitude of the drug manufacturers whose arguments spread another form of intransparency, because they emphasise nothing but the possibility of cost increasing effects caused by a positive list. Such an effect would, however, not fit into the current situation and framework conditions of the Federal Republic, since everybody tries to find ways for reducing costs in the health sector. Positive lists per se are certainly not a cost-reducing instrument – they are instruments to promote market transparency and thus the manageability of the drug supply. An oversupply of drugs is not only counter productive to clinical freedom – an oversized drug market hardly allows a therapeutical decision of the individual doctor based on comparative information –, it also jeopardises drug safety, because an overflowing drug market no longer permits efficient monitoring and control. Restricting lists will thus become the prerequisite for a wisely used clinical freedom, for attempts to achieve drug safety and for prescription quality – all of them being determinants of a rational drug therapy.

Jane Moffat

EDLIZ – the essential drugs list for Zimbabwe

Background

I was recruited by the University of Zimbabwe to develop their National Drug and Toxicology Information Service at the beginning of 1983. Before that I had worked as a drug information pharmacist in the UK National Health Service, and had just completed a postgraduate course in information science which included the development of skills such as technical writing, editing and print production.

Zimbabwe had attained independence less than 3 years previously, after a long and bitter struggle against the white minority government of Ian Smith. At independence in 1980 there had been a radical change in health policy to counteract the existing inequities in health care provision between different sectors of the population. There were severe problems in infrastructure as many clinics and rural hospitals had been destroyed or rendered unusable during the liberation struggle. There were also shortages of essential drugs caused by factors such as foreign currency shortage, use of available foreign currency to import inappropriate drugs, and by problems of distribution of drugs to outlying areas from the central Medical Stores.

At the time of independence there was also an exodus of white professionals from the country, although this was to some extent offset by an influx of returning Zimbabweans including health professionals trained overseas and ex-combatants with nursing and paramedical training, and of expatriates – many of whom were sympathetic to the goals of the new government. There were necessarily many changes within the Ministry of Health at that time, but one institution which remained relatively constant throughout that period was the Drugs Control Council, responsible for registration of drugs and implementing legislation, which continues to make a major contribution towards preventing the manufacture or importation of unsafe and unnecessary drugs in Zimbabwe.

The Proposed Essential Drugs List for Zimbabwe – PEDLIZ

In 1981 the Ministry of Health published the Proposed Essential Drugs List for Zimbabwe, written by the National Drugs and Therapeutics Policy Committee (NDTPC) made up of doctors and pharmacists from the Ministry of Health and the Medical School of the University of Zimbabwe. This was an innovative publication containing therapeutic guidelines for treatment of common medical conditions, and a list of recommended drugs for general and specialist use. The selection of drugs was based on the WHO list, but influenced by local prescribing practices and local availability. This was a very positive publication which assisted in the management of the increased workload of the government health service, and provided locally relevant prescribing advice for health workers who had trained in other countries. The Ministry of Health openly acknowledged that there may be omissions, stressing that this was only a proposed list. PEDLIZ thus served the dual functions of a useful text and a discussion document. Adherence was not mandatory, and a review after 6 months was promised, with revision and expansion to form the Zimbabwe National Formulary which would then be reviewed annually.

The NDTPC requested comments to enable a meaningful review to be undertaken, and provided the appropriate forms in the back of the book for suggestions of:

– modifications to treatment regimes

– additional regimes to be included

– drug additions, deletions and substitutions.

In reality there was a disappointing response. Few comments were received, the majority coming from the local drug industry.

With hindsight, the promised reviews represented an over-optimistic goal. The necessary bureaucracy would take longer than 6 month in most countries, and perhaps even longer in a developing country, especially if the finished product is to be of good quality. Whilst these promises served to encourage enthusiasm for the new publication, this turned into growing impatience and dissatisfaction as the review exercise dragged on a long way past its proposed target.

The production of the Essential Drugs List for Zimbabwe (EDLIZ)

The review exercise involved

– revision of PEDLIZ treatment regimes

– addition of new regimes, including oral rehydration therapy, immunisation, tuberculosis, leprosy, oral contraception, drugs in pregnancy and lactation, treatment of poisoning, paediatric dosage

– revision of the drugs list

The committee was aware of the need to make the book locally applicable and so for example the section on sexually transmitted diseases based its diagnostic criteria on clinical symptoms rather than on laboratory diagnosis, as such facilities are not available to the majority of local clinics.

There was a liaison with the government Medical Stores and the Drugs Control Council to ensure that the recommended drugs would be available locally. The drugs list of just under 500 preparations was annotated to indicate which drugs would be available for use at the various levels of health care facility, with small clinics run by nurses having access to fewer drugs than hospitals with doctors in attendance. There was also a list of drugs for use by village health workers. In some cases a drug group rather than an individual drug appears on the list to enable competitive tendering for the government contract (eg for a broad spectrum anthelmintic), and prevent over-pricing.

The committee approach

The committee was able to include locally respected experts from the medical fields, together with key figures from the Ministry of Health, as all the major government offices and the Medical School are situated centrally in Harare. Meetings were thus relatively easy to arrange, and fairly well attended. There were of

course problems with access as well did not attend regularly, causing duplication of work at subsequent meetings. The committee did not initially appreciate the need for an editor, and assumed that the committee secretary, a pharmacist with no specific training or skills in that area, would be adequate. There was also a lack of awareness of the importance of good presentation in terms of appearance, size, layout and indexing.

Problems in editing EDLIZ

This required a great deal of work in unifying the styles of presentation and terminology of the various contributors if the book was to have any cohesion between sections. In some cases the language had to be simplified—including the removal of various Latin phrases from one section. Some contributors seemed unaware that for the majoritiy of the book's users, English itself was a second language. The onus was also on the editor to ensure that the final drafts had the overall approval of the original contributor and the committee.

Fortunately a word processor was available, which greatly facilitated the production of drafts, modifications, and design of layout. The final text has been stored on disc to enable subsequent editions to be produced more easily. The final draft was eventually agreed by mid 1984, nearly 3 years after the original publication.

Printing

The printing of the book proved to be the most frustrating task of all, due to difficulties with the printers. Although the job had been thoroughly discussed with them, and a high quality manuscript had been provided, problems of typographical and layout errors seemed unsurmountable at times. Proof reading also posed problems due to the large number of errors, and lack of experienced proof readers with the appropriate technical background. After these difficulties had been overcome, there was then a problem of finding suitable paper and cover material, as by that time the paper which had been promised had been used for another printing job. The materials used had to be durable enough to withstand heavy usage. The final problem was in the size of the print run which was far too small. There were barely enough copies for the initial distribution of the book, leaving almost no spare copies for sale or for issue to staff joining the government service subsequently. For the book to be of maximum benefit it must be available at the point of use—in the user's pocket—one copy per ward or clinic is not enough.

The launch of EDLIZ

It had taken 16 months from the delivery of the manuscript to the printers until the official launch in late 1985. A high profile approach was adopted, with the Minister of Health appearing on television to launch it. In his speech he stressed the positive aspects of EDLIZ in terms of its potential to bring about an overall improvement in the standards of health care, and further the aim of health for all by the year 2000, rather than being a restrictive list.

Usage and acceptability of EDLIZ

There were no major problems in acceptance of this 'limited list' of prescribable drugs. The majoritiy of users were nurses and medical assistants, who were in need of the therapeutic guidelines, and were happy to know which drugs would be routinely available for them to use. Drugs not included on the list were simply not available except perhaps in the specialist hospitals. (Due to recurring drug shortages in Zimbabwe, the majority of health workers were already used to substituting drugs on a regular basis.)

What lessons can be applied to the European situation?

1. Who decides the content of the formulary?

   Must be a committee approach, with all its inherent difficulties. Members must be locally respected experts in their field in order to have credibility.

2. Visual presentation

   The formulary must look good. Need expertise in presentation—book must be easy to read and use, and must be well indexed.

3. Publicity of the formulary

   Must stress positive consequences of formulary use—therapeutic advantage is of paramount importance. Cost saving is a welcome side effect.

4. User consultation

   Regular reviews are essential, incorporating user suggestions where appropriate. First editions are likely to have unforseen problems—important to have a second edition within reasonable time.

5. Flexibility to incorporate new drugs

   There has to be a system whereby a new drug, if it represents a real therapeutic advance (this is rare!) can be used if necessary.,

6. Local relevance

   Of particular importance for users coming from other areas—not just internationally but regionally. The formulary must address local health problems for example tuberculosis, thalassemia, sickle cell disease etc. where appropriate.

7. Education of users

   This should start during training. Doctors will be educated by their consultants, so the attitude of senior medical staff is of

utmost importance. We also need to educate pharmacists, as they are the ones who generally have to police the implementation of a formulary. They need information back-up on why the particular drugs in the fomulary were chosen to enable them to 'sell' the formulary idea, especially when discussing problems with prescribers and when counselling patients. Their attitude can determine the success of a formulary.

Why the task is more difficult in Europe

It must be borne in mind that there will be different attitudes to the use of formularies, caused by the vast difference between the standards of health care already achieved in Europe and in developing countries. In most countries health budgets are limited to varying entents, and there is an extra restriction in countries with limited foreign currency resources. Developing countries represent the extreme end of the system of limited resources, and necessarily adopt a hard line approach when attempting to rationalise prescribing, which is acceptable to the majoritiy of health workers in that situation. The provision of expensive anticancer chemotherapy for example would be difficult to justify until a reasonable standard of primary health care and immunisation can be provided for the general population. It is for these reasons that I feel we in Europe must be selective in the lessons we can learn form the experience of developing countries in rationalising drug treatment.

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Dr. Gaut Eadelholt

The Norwegian need clause: Effects on prescription practices

The Norwegian law of drugs says:

§15. Pharmaceutical preparations must be approved by the specialities comittee. Approval is given based on the type of preparation, composition, quality and stability. Approval shall only be given for preparations that are considered medically justified and for which there is an assumed need.

§17 . . . approval is given only for 5 years at a time and can be withdrawn (inter alia) if the drug no longer is considered medically justified. In some cases approval may be on condition that the preparation should be prescribed only by certain hospitals or physicians.

The law has, as you can see, two basic requirements: Medical justification and need.

Medically justified means that the drug has a demonstrable beneficial effect as claimed and that the side-effects are acceptable compared to the seriousness of the condition to be treated.

Medical need is present when the present treatment is ineffective, has too many side-effects or is too expensive, and it is not present if the present treatment is satisfactory or if a new drug offers no improvement in either performance or price compared to the present treatment.

Practical consequences:

The law states that only effective drugs should be marketed, and the need clause gives legal backing to keep down the number of equivalent effective drugs. In a way it may help keep the number of drugs down, but it also limits competition on the market when there are a sufficient number of preparations already on the market.

This gives legal backing for avoiding registration of drugs that are medically justified and would have been approved if they had been among the first on the market.

Present status is that Norway has about 700 active substances, 1100 brands and 2000 dosage forms (4000 when different brands are considered). I shall briefly review ATC- groups with the largest number of equivalent drugs.

A: Alimentary system

4 sulfonylurea antidiabetics: Tolbutamide, glibenclamide, glipizide, chlorpropamide.

There are several insulin preparations which appear to be equivalent.

C: Cardiovascular system:

The situation may reflect the considerable pressure on this market.

5 nonselective beta blockers: propanolol (3 brands), pindolol, oxprenolol, alprenolol, timolol in addition to 3 selective beta blockers (atenolol, metoprolol, and practolol) (for injection only) and labetalol, 3 brands of verapamil

4 thiazide diuretics, and 3 nonthiazide low-ceiling diuretics

6 brands of oral furosemide(!)

9 glycerylnitrate preparations (tablets, aerosols, plasters etc)

7 antiarrythmics (Lidocaine, procainamide, quinidine, disopyramide, mexiletin, tocainide, flecainide) (+phenytoin)

And 2 ACE inhibitors, 3 calcium antagonists.

D: Dermatology:

15 topical corticosteroids in the 4 strengths (+ combinations)

J: Anti-infectives:

6 oral penicillin V preparations

4 aminoglycoside antibiotics

6 cephalosporins

2 macrolides (2 brands of erythomycin)

L: Cytotoxic drugs:

(Much of cancer chemotherapy is still experimental, and this may be reflected in the number of drugs.) 26 alkylating and non-alkylating drugs + asparaginase and tamoxifen

N: Central nervous system:

Here the number of drugs seems large. 19 neuroleptics (and 3 chlorpromazin preparations)

9 tricyclic antidepressants

10 benzodiazepines

6 narcotic analgesics + fentanyl, propoxyphene and pentazocin

5 anticholinergic antiparkinson drugs

M: Musculoskeletal system:

8 nonsteroid anti-inflammatory drugs (+ 8 acetylsalisylic acid preparations)

2 gold preparations (1 oral and 1 parenteral)

R: Respiratory system

4 $ß_2$-stimulators for inhalation

8 H^1 antihistamines + 3 phenothiazines + cyproheptadin

There are two points of all these details: the restrictions have not deprived Norwegians of suitable drugs. On the other hand, even

with the need clause there are too many drugs. The need clause has not been used strictly in all therapeutic groups. But the number of active substances and brands would undoubtedly have been higher if there had been no need clause. The result of a registration application is dependent on the consultants used. The infections people have been restrictive; the psychiatrists have been more liberal, as you can see from the difference between the anti-infecitves group and the central nervous system group.

Statistics on rejected applications 1981-1983. Total number of applications was about 200. 40 percent of the applications were rejected. In more than 60% of these need considerations were involved.

Latest report on rejected applications for registrations of drugs (1985; published 1987).

27 preparations

11 were rejected only because they were considered unnecessary.

3 were new benzodiazepine hypnotics (10 benzodiazepines are on the market for different indications)

3 were nonsteroid anti-inflammatory drugs of which there are already 8 active substances on the market

2 cephalosporin antibiotics (of which there are 6 on the market)

1 antimycotic-corticosteroid combination (of which there are 2 already on the market)

1 trimetoprim-sulfadiazine preparation

1 cisplatin, 1 verapamil, 1 ibuprofen which are already on the market in other brandnames.

Need considerations were used in the rejections of two additional benzodiazepine hypnotics, one beta blocker-diuretic combination, one topical antimycotic, one coagulation factor preparation. Need considerations were involved in 60% of the rejections.

The others were rejected because of undocumented efficacy or unacceptable toxicity, i.e. because they were not medically justified.

Fixed-dose combinations, are mainly rejected because they are not shown to be medically justified. There are some on the market.

Requirements are

(medical justification) that each component should contribute to the claimed effect. A component may enhance effectiveness or safety or minimise abuse. There should be similar pharmacokinetic properties of the components.

AND

(need) A reasonable number of patients should benefit from the combination.

Registered fixed-dose combinations: Codeine – paracetamol

Amiloride – hydrochlorothiazide
Trimetoprim – sulfametoxazol
Diuretic – potassium chloride
Penicillin G – Local anaesthetic
Topical corticosteroid – antiseptic/antibiotic/antimycotic
Phenylpropanolamine – antihistamine

Chlorzoxazone – dextropropoxyphene – acetylsalicylic acid
Carisoprodol – paracetamol – caffeine
Phenprobamate – acetylsalicylic acid – codeine
Ergotamine – butalbital – belladonna – caffeine
Ergotamine – meprobamate – chlorcyclizine – caffeine

The latter five combinations do not fill today's requirements and would not be accepted today. You can see below that more reasonable combinations were recently rejected, mainly because of poor medical justification.
Atenolol – chlorthalidone
Captopril – hydrochlorothiazide
Trimetoprim – sulfadiazine: This combination was found to be medically justified for urinary infections, but there was no need for the preparation in urinary infections.

CONCLUSION:

The need clause and other elements of the Norwegian drug law have kept the number of drugs on the market in Norway lower than in many other countries. On the other hand there appears to be full coverage of valuable and well documented drugs so that the health system has a supply of all the drugs that are needed. Even the Norwegian drug market has too many drugs and brandnames, and there are a number of poorly documented or irrational combinations. If an individual patient needs an unregistered drug, a doctor may apply to the Drug Control Authority for permission to prescribe the drug to the patient on an individual basis. Reasonable applications are usually granted. (Recently, the largest number of such prescriptions were nonsedative antihistamines, but terfenadine is now registered.) In these cases the prescribing doctor has wider responsibility than with registered drugs.

"A world of mutual dependence"

"Essential drugs" – is this only a concept for the Third World? Gerd Glaeske spoke with Dr. Zafrullah Chowdurhy from Bangladesh where the WHO strategy has already been implemented to a large extent.

Q: In West Germany we have an abundance of drugs on our market which is difficult to control. The Conference organized by the Pharma Campaign of the Federal Congress of Development Action Groups (BUKO) in Bielefeld was placed under the motto: „Learning from the Third World". What can we in West Germany learn from your experiences in Bangladesh with regard to a regulation of the drug market?

Chowdurhy: The drug market in the Federal Republic of Germany reflects the enormous power of the pharmaceutical companies over politics in West Germany. It is always a bad thing if someone holds a monopoly in any country. In our interest as well as in the interest of the population of West Germany it must be stated that basically, the existence of too many drugs leads to too many problems. The number of drugs must be reduced, e.g. by means of a positive list.

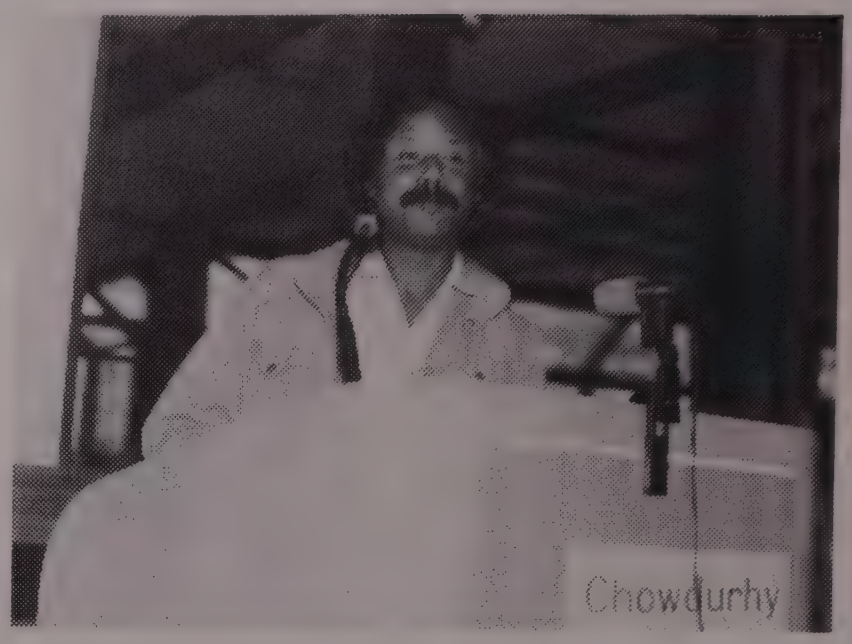
Q: Do you think that a positive list or a limited list can be a solution to the problems on the drug market – and this not only in the Federal Republic of Germany?

Chowdurhy: I feel that limited lists would be a solution for all countries. However, they should apply to all fields, i.e. to the public as well as to the private sector. This is an important aspect to be taken into account because otherwise you might easily make a big mistake. For if you only have a limited list for the public health service people have the impression that there are limited lists for the poor and unlimited drugs for the rich. This does not result in better medicine.

Q: What are the consequences for Third World countries if there are no limited lists in the industrialized countries?

Chowdurhy: This has grave consequences for two reasons: First: The Federal Republic of Germany and other industrialized countries have a developed industry and developed technology. We are worried that West German companies and companies in other industrialized countries also distribute their bad products. People tend to believe that products sold on the West German market must be good. The mere fact that a drug is available in West Germany or in any other industrialized country influences and impresses many politicians and doctors in the Third World.

Second: The bad drugs are exported to our countries. These drugs are also available in West Germany but people use them more rarely, because you have many doctors in your country and people can make use of an existing health care sytem. If they need some medicine they often get a prescription from their doctor. In poorer countries drugs are often sold in the „free" market and pharmaceutical companies encourage this self-medication.



Q: That means we need a strategy that can be applied in industrialized countries as well as in developing countries.

Chowdurhy: That's right, in particular because we are heavily dependent upon each other. In the sixties, seventies, and eighties West Germany has emerged as an important power on the world market. It gives economic and technical assistance and there are contacts of economic experts and scientists. This is very important, but it also implies that the country must set an example. This is why it is indispensible that, if we want to have drugs of good quality in our countries, the drugs sold in West Germany must also be of good quality. Due to the external contacts the situation in West Germany always has an impact on other countries. We live in a world of mutual dependence.

Q: There are many solidarity groups in West Germany who collect drugs and send them to developing countries. Do you regard this as a useful aid?

Chowdurhy: The problem is that in spite of the good intentions of those collecting the drugs we also receive bad things. Besides, names are exported. We do not get a certain substance but a product of a certain pharmaceutical company. Sometimes there are also some language problems with regard to the package inserts. These package inserts are not always intended for the countries which recieve the drugs and many people cannot read the drug information. It is better to enable the respective countries to carry out bulk purchase of substances or set up their own drug production by providing them with financial aid.

This interview was made at the conference and first published in: Demokratisches Gesundheitswesen, FRG, Dec. 87, pp 14 – 15

Günter Lewandowski

A rational drug policy for Europe from the industries point of view

Thank you very much for the cordial welcome. I am glad to be here and to be able to give a short talk. I hope that we will have an interesting discussion even though it might sometimes be a controversial one. In my presentation I want to point out once more some aspects which you might take for granted but maybe there will also be some remarks that appear provocative to you. However, it is not my intention to provoke you but to seek after the truth. And later we can dispute about the different kinds of truth.

In my opinion a rational development, manufacture, marketing and consumption of drugs must meet certain basic criteria on which, as far as I know, there is a general agreement among the parties concerned.

– pharmaceutical quality

– therapeutical efficacy

– safety

– therapeutic value

– medical need

– economic efficiency (favourable cost/benefit relationship)

are the criteria determining the value of a drug at all development stages and the product stage. I usually refer to them as the social criteria of drug evaluation. The first three of them, i.e. quality, efficacy and safety, are required for approval in most countries. The remaining three are required to a lesser degree and in my opinion they cannot be required in the same way as the first three criteria. It is only reasonable – and nobody should dispute that – if drugs are to meet a medical need but it is very difficult to make a need clause work in administrative practice.

The decision on whether quality, efficacy, safety and other criteria have been fulfilled comprises different elements and requires the collaboration of different professions and disciplines. Instead of having one discipline claim to be the sole representive all disciplines should be involved in the evaluation process. Chemists and pharmacists, toxicologists and pharmacologists, clinical pharmacologists and of course supervisors of the different disciplines are primarily involved.

When enumerating different medical disciplines I do not unnecessarily repeat a truism. A critical look at the public debate on drugs reveals that there is not only a controversy between industry and authorities or between the medical field and marketing but that there is also a controversial evaluation of drugs within the medical sector. It seems to me that there is unfortunately a lack of communication between the different disciplines of the medical profession, i.e. between hospital doctors and general practitioners, between toxicologists, pharmacologists, drug epidemiologists etc. To put it a bit more bluntly or provocative: We must take care that the clinicians do not forget the side-effects and that the pharmacologists do not forget the patients. For years industry has made the mistake to base its evaluation of drugs on the opinion of clinicians who spoke out in favour of a certain drug. Much too often and much too long pharmaceutical companies have disregarded clinical pharmacology and drug epidemiology. However, a responsible drug manufacturer must include the whole medical spectrum in his decision-making process and he must be willing to make contribution to a better communication between the different disciplines.

The decision on whether the already mentioned criteria of quality, efficacy, safety, etc. have been fulfilled is not only of a purely scientific and technical nature. To begin with, a necessary scientific and technical decision-making process is often impeded by uncertainties. We do not deal with mathematics, theoretical physics or mechanics but we largely deal with biological processes. In this respect our knowledge is often fragmentary, data

and opinions are contradictory and usually we have to be content with probability judgements. In addition to this there is a large degree of value judgements and value decisions centre on: Can we accept the risks of a certain drug? This question cannot be answered with one discipline having the sole right to make a decision. The decision on the acceptability of a risk compared in a democratic society can only be made after a public discussion involving all parties concerned. We do not only have to see to it that all disciplines are involved in a scientific and technical evaluation process but we must also face public criticism and the public decision on drugs. Reasonably enough authorities make their decisions after a public hearing and it is manufacture's duty to cooperate actively. In my opinion this includes the participation in discussions like this one today. Unfortunately, companies still exercise restraint.

The European pharmaceutical industry must take responsibility for a more rational drug policy by supplying the market with drugs which meet the above-mentioned criteria at the level of development, manufacture, distribution, pricing, application. There are many controversies in this respect, and this is why specialists and politicians must always try to reach consensus.

Within the framework of your conference the following question must be asked: Does a reduced number of drugs and thus a limited drug supply contribute to better drug safety or is a reduced number of drugs irrelevant to drug safety? Is the number of drugs sufficient or insufficient? In my opinion the large number of drugs and the glut of drugs evidently make it more difficult for doctors, patients, scientists, and authorities to gain knowledge about the benefits and risks of drugs. The unmanageable number of drugs makes it more difficult to achieve a better

and safer therapy. It is easier to study two drugs than 200 drugs. This is a simple arithmetical problem. However, I am always a bit careful with regard to drawing simple conclusions like this one and I have never been convinced that the problem can be easily solved by simply reducing the number of drugs for it is the above-mentioned criteria which are decisive for the quality of a drug. If these criteria are met at the stage of development, manufacture, distribution and application the number of drugs is no longer important. A restricted drug policy merely aims at achieving a better and safer therapy. I feel – and this is a hypothesis I want to put up for discussion – that nature is always very complex. Remember the many different varieties of plants and animals for the preservation of which we work. And maybe the variety of substances available in the medical field is more useful than the existence of only few substances and I believe that there are quite a few examples for this in the medical field. In the case of allergic reactions or resistance the variety of substances is indeed a solution or an extension of therapeutic possibilities. There is no doubt that many useless, obsolete and even mystical drugs are offered on certain markets and that the transparency of the drug supply, i.e. the sufficient knowledge of the doctor or the patient about drug properties and prices, has not yet been achieved. I feel that it is immoral to take advantage of ignorance, and misguided behavior has also been detrimental to industry as a whole and, of course, to patients. Today we have the possibilities to bring about an effective change.

I believe that a reduced drug supply can only be accepted as an ultimo ratio. (It goes without saying that drugs of insufficient quality, efficacy and safety must be removed from the market.) Bearing in mind our present technical possibilities it is better to concentrate on achieving more transparency with regard to positive and negative effects of our drugs and to distribute and apply the transparent knowledge. This is more difficult but I believe that it is more useful for therapy. It would also be good if we resisted the temptation to take our job of a policeman responsible for drug control too lightly. In a dictatorship the censor dreams of having but one monthly newspaper. This will make censorship much easier but it hardly contributes to public discussion or to the further development of literature. A reasonable middle course must be found. Drug control is necessary and it must be effective, radical and exemplary. However, the main aim is a safe therapy and not an easily controllable glacis for vigorous policemen.

Do fewer drugs result in better therapy? Can we learn from the Third World? My answer to these questions: There is no doubt that we can learn a great deal from the Third World. These countries have a impressive culture and there is no reason for us to be presumptuous when dealing with the civilization and cultures of Third World countries. On the other hand, there is no reason for us to have a guilty conscience because of our modern therapies. It is true that we must continue to develop and improve them, that we must remedy grievances and that we must achieve a more rational use of drugs but I am absolutely convinced that with regard to therapy the efficiency of Western countries and Western medicine is bigger and unchallenged. To put it briefly: It is not fewer drugs which result in better therapies but it is better knowledge and an improved application that lead to better treatment.

It cannot be denied that the individual doctor does not need all the drugs available on the German or American market. It is certainly correct that an individual hospital, an individual general practitioner or a specialist can manage with a relatively limited drug supply which is only a fraction of the drugs available on a developed market. The important point is that the doctor has all the information he needs and can decide himself, that the hospital has all the information it needs and can decide itself which therapy is most appropriate. It is also important to note that there can certainly be some competition in this field. It makes a big difference if, for example, a hospital decides to limit itself to 200 drugs or if a doctor decides to limit himself to this number of drugs or if all doctors or hospitals in a developed country with a highly sophisticated medical sector are obliged to use no more than 200 drugs. This is why I think that the question of drug-variety should be answered pragmatically and with common sense. This is not always easy and it is not easy to explain because we often tend to see things in black and white but sometime truth can be found midway. At least this is what I feel.

Let me conclude by putting forward some theses: The most important obligation the pharmaceutical industry has to be undertake is the supply of drugs of a therapeutic value at economically favourable conditions and in critical consideration of aspects concerning science and medical practice. In this respect a lot remains to be done. Development and manufacture does not only mean the development and manufacture of a substance but also of information because a drug is not only a chemical but a substance plus information. A patient cannot only be killed by a chemical substance but also by insufficient drug information. If we have industry as well as by other institutions it would be bold to claim that there are no possibilities and no need for improvements. There is a need for improvement and there is a lot of promotinal rubbish which is economically useless, which prevents a transparent drug supply and which – and here I speak from the point of view of industry – unnecessarily questions the credibility of drug manufacturers.

My second thesis is the following: In my opinion European industry is obliged to support a common European market with a uniform European licensing and drug control system. The present national fragmentation is an anachronism hampering drug development as well as a rational use of drugs.

Finally we must honour our political commitments to the Third World by considering their needs more than we do at the moment. The cooperation with WHO and other UN organizations is a simple must. The whole-hearted support of WHO policies such as the Revised Drug Strategy is a self-evident obligation.

We must be open and we must be willing to discuss things which does not mean that we discuss only for the purpose of propaganda. On the contrary, we must strive for a consensus even if might sometimes be difficult.

Thank you very much for your kind attention.

Dr. K. Balasubramaniam

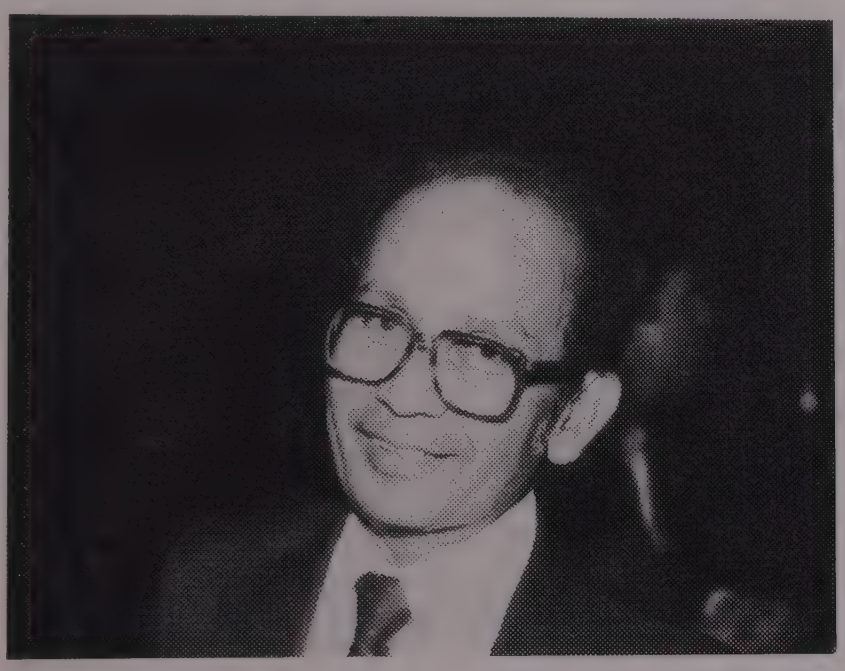
The rational use of drugs – a universal concept

A. Introduction

The title of my presentation is deceptively simple. Rational use of drugs is a concept on which there is universal agreement. No one will ever argue for the irrational use of drugs. Then why do we have such a paper at this International Conference on 'Fewer Drugs, Better Therapy: Learning from the Third World?'

Do the organisers believe that in spite of the universal consensus, not many countries are using drugs rationaly? It would appear so. The conference starts with descriptions of the chaotic drug situation in both industrialized and Third World countries.

The main theme of the conference suggest that rational use of drugs, among other things, involves using a limited number of drugs. Let us examine how far countries have been successful in limiting the number of drugs marketed.



The UNICEF annual report for 1986 states that 98 developing countries have instituted essential drug programmes an 29 of them are fully operational. It would appear that these 98 countries or at least 29 have instituted national drug policies based on the concept of essential drugs. It will not be possible for a country to implement an essential drug programme without an integrated national drug policy. However, a WHO document (WHO/CONRAD/WP/R1, Page 2) states that in both developing and developed countries, a comprehensive national drug policy forming an integral part of a well defined national health policy is the exception rather than the rule.

This apparent contradiction between two reports may be explained as follows:

Though 98 developing countries have introduced essential drug programmes, these programmes are confined to the public sectors only[1]. The private sectors continue to market thousands of formulations. In the vast majority of developing countries the private sector controls the major share of the drug market (Annex 1). The public sector contribution is small and any rationalising of this sector makes very little impact on the overall pharmaceutical supply system. It may be possible that the WHO report on the absence of comprehensive national drug policies in developing countries reflects the lack of control over the private sector.

The initiative of Health for All by the year 2 000 and the programme of essential drugs are largely viewed as relevant only to Third World countries although there is official endorsement of these aims by advanced industrialised countries. A senior WHO offical in the pharmaceutical unit has recently expressed concern as to whether an essential drugs concept could be universally applied. However, because of the large numbers of existing 'me too' drugs (e.g. around 70 corticosteroids and more than 50 beta blockers), there is a need for a 'rational drug list', he added[1].

Factors determining drug availability and drug use

Analysis of the drug situation in both developing an developed countries reveals that the major factors determining drug availability and use include:

1) The prescribing practices of doctors

2) The structure and operational activities of the drug industry

3) Effectiveness of the drug regulatory authority and

4) Political will

B.1 Prescribing practices of doctors

Many doctors believe that clinical freedom is a sacrosant right. Clinical freedom is the right of the doctors to do whatever in their opinion is best for the patient. In days when drug treatment was as harmless as it was ineffective, the doctor's opinion was all that there was. But todaytheir opinion is not enough.

It is difficult to agree that the average doctor is aware of the latest information on drugs including data on clinical trials and bioavailability studies. More importance is given to these data in the evaluation of drugs than the experience of physicians, who are now losing theirt earlier total power in the selection of drug preparations. This power is now transferred to expert committees and political bodies.

The medical profession has always preferred to travel hopefully than to arrive because arrival is so often disappointing. This leads to oscillating fashions in treatment. There always seem to be some current fashion in treatment. Before the current fashion is evaluated, another one takes its place. A doctor with any pretentions to being a clinical scientist might be embarressed at the way many doctors have responded to new drugs and new innovations in the past 3 to 4 decades. All too often they have behaved like children who see new toys. They want it immediatley. Very soon they discard it for another. Clinical freedome, some critics have argued, at best is a cloak for ignorance, at worst an excuse for quackery.

Doctors who argue for an unlimited number of drugs insist that they do so on the basis of scientific evidence and not on account of commercial pressures. The nature of drug advertisement is that doctors often deny the relative importance of commercial sources influencing their prescribing.

A survey was done in Boston, Massachusetts in the early eighties to study the perceived sources of influence on physicians' prescribing practices and their beliefs about the use of drugs[2]. The selected drugs for the survey included cerebral and peripheral 'vasodilators' for which messages about therapeutic efficacy differed substantially between scientific and commercial sources.

These drugs are widely promoted by manufacturers for senile dementia and peripheral vascular insufficiency but clinical litera-

ture overwhelmingly indicates that these drugs are ineffective for these indications[3,4]. In the management of senile dementia, industry advertisements are the only sources of misinformation which claims that mental failure in the elderly is the result of inadequate blood flow to the brain—a concept now abandoned by neurologists and internists[4-7].

In the survey a sample of doctors were asked how important selected sources of influence were on their prescribing. The answers fell into three categories: very important, moderately important and minimally important.

Table 1 gives data on the relative importance of different sources of information which doctors perceive influence their prescribing.

Table 1

	Perceived influence on doctor's prescribing		
Sources of Influence	% responding very important	% responding moderately impt.	% responding minimal impt.
Drug advertisement	03	28	68
Detailmen	20	26	54
Scientific papers	62	34	04

Sources: Avorn et al 'Scientific versus commercial sources of influence on the prescribing behaviour of physicans.' American Journal of Medicine, July 1982, Vol 73, pages 4-8.

This table shows that the majority of doctors perceive scientific journals to have a very important influence on their clinical judgement and prescribing habits; advertisements and detailmen, on the other hand, play a minor role.

This sample of doctors were asked to respond to a question, 'Is impaired cerebral blood flow a major cause of senil dementia?' Table 2 gives the response of the doctors.

Table 2

Answers to the question, 'Is impaired cerebral blood flow a major cause of senile dementia?'

	Percentage response
Yes	71
No	14
No opinion	15

Sources: Avorn et al 'Scientific versus commercial sources of influence on the prescribing behaviour of physicans'. American Journal of Medicine, July 1982, Vol 73, pages 4-8.

The data in tables 1 & 2 show that the doctors beliefs bore no relations to their perceived sources of information. Although the vast majority of doctors perceived themselves as paying little attention to drug advertisments and detailmen as compared with papers in scientific literature, their beliefs about senile dementia revealed the quite opposite pattern. This happens not only in Boston, but in Brazil too, where the cerebral 'vasidilator' drug Hydregine was one of the top ten best selling drugs in Brazil[8].

In addition to being influenced by drug advertisements, there is concern that some doctors may not be heeding the warning by drug regulatory authorities. In the Federal Republic of Germany, the BGA (Federal Health Authority) in 1978 pointed out that sex hormones administered during pregnancy cannot prevent an abortion and warned that these hormones could increase the risk of limb birth defects in the foetus by a factor of 4.7. In spite of this warning, it has been reported that sex hormones (particularly Gestanon, Gravibidon and Duphaston) are prescribed about 50 000 times annually[9].

A new development between the industry and the medical establishment is causing concern. Large international scientific congresses have in many cases acquired the characteristics of a profitable commercial enterprise. At a recent world congress on cardiology in Washington, drug companies were required to pay around one hundred thousand dollars if they wished to hold a satellite symposium. The cost of scientific meetings tend to be funded from drug companies' research budgets[10].

Science and marketing methods are incompatible bedfellows. Doctors seem to be remarkably simple minded not to recognise this inverse co-relation between the two.

B 2) The structure and operational activities of the drug industry

Public health is now recognised as a fundamental right. Its attainment has become a social responsibility. However, the provision of medicines remains almost exclusively in the domain of the private industry. There is a conflict of interests between the social objectives of governments wishing to provide health care services to all the people at costs they can afford and those of the drug industry geared to increasing profits and market shares.

As far as the industry is concerned, marketing means bringing the needs of the ill in harmony with the economic objectives of the manufacturer, and economic objectives clearly dominate. Governments, in making the needs of the people a priority, take measures to protect the people from the pressures of commerce by drug control an regulatory measures.

The industry strongly believes that drugs should move in a free market without controls since regulation makes the market ineffective. There are many buyers, many sellers, many products, no natural monopolies and no obvious cartels. Therefore, there will be ample competition. A competitive market system, the industry argues, is the basis for innovation and growth of the industry.

Proponents of a free and competitive market maintain that the standard economic approach is to rely on signals sent by market forces. Consumers are expected to have well-defined preferences and are assumed to be able to choose from a variety to suppliers of the goods and services they need. In doing so they will produce their goods at the minimum possible cost and offer a range of qualities that consumers want to purchase; otherwise another supplier may take his business away. If there is an inefficient group of suppliers in an industry, it is assumed that firms from outside the industry will enter the market in pursuit of profits to purchase with their incomes are produced at minimum cost[11].

The pharmaceutical market is far removed from the above model in many respects:

a) The patient (consumer) can never choose the best form of therapy; the basic assumption of consumer sovereignty does not therefore apply in the pharmaceutical market;

b) From the buyer's point of view (in this case a doctor's) a market is the availability of substitutes or alternatives. How true is this in the drug market? For an individual clinician the different brands of a single substance may be the only substitutes under consideration; it is even doubtful whether some physicians will consider different brands as real substitutes.

c) There is no standard guideline in therapeutics. Instead there are a variety of acceptable treatments. The physician has, therefore, a wide latitude in his choice of therapy.

d) The physician is not rewarded for cost-effective prescribing.

e) The more goods and services a dispensing doctor in private practice provides, the higher is his income.

Taking (b)—(e) above into consideration, it is clear that the persons who convert the consumers medical needs into demands and act on behalf of the consumer will not choose the lowest cost supplier. Again the validity of singnals sent back by the market forces go overboard, and

f) Firms outside the pharmaceutical industry can never enter this market.

The pharmaceutical markets both in the developing countries and in the industrialised world are therefore in no way competitive markets. The TNC model for the pharmaceutical industry is bound to fail if the development objectives of countries are to ensure a growing supply of a limited number of essential and life-saving drugs at reasonable prices to the whole population. The objectives of meeting this social responsibility can be achieved only if both the product mix and the pricing structure are regulated to secure a better convergence of commercial considerations and social needs and priorities.

The so called innovative activities of the research based pharmaceutical industry have resulted in large numbers of essentially interchangeable products which render therapeutic comparisons impracticable. They create a situation in which therapeutic choice is determined by promotional pressure rather than by objective evidence and in the long run threaten to frustrate evaluation of therapeutic performance[12]. From society's point of view, drug markets behave irrationally since commercial information influences the selection of drugs much more than the data from clinical investigations and prices.

The influence of commercial pressure on drug selection is more marked in Third Word countries than in the advanced industrialised countries. In the latter, there are security nets to prevent overstatements contained in advertisements for drugs. Consumer, political and professional groups can mobilise enough power to counteract industry propaganda. Furthermore, formal drug legislation also exerts effective control. Several countries in the Third World lack these protective mechanisms. Professional an political organizations are too weak to criticise the behaviour of big drug multinationals. To criticise such a company may destroy a promising professional career.

B 3) Effectiveness of the drug regulatory authority

The dramatic contrasts sometimes quoted between Germany's (FRG) 120,000 drug specialities and Iceland's 1,180 reflect the different attitudes to drug regulation[13]. In fairness to the German regulators, it must be stated that not all the 120,000 products are modern pharmaceuticals but include homeopathic drugs, drugs prepared and sold in a single pharmacy, and herbal teas[14]. The functioning of the regulatory agencies in the advanced industrialised countries is to a considerable extent dependent on the size of the pharmceutical industry in the country concerned. In countries like the UK, USA, FRG, France and Italy, the drug regulatory agencies have of necessity very close contacts with the drug companies in these countries developing new drugs. Safety rather than need and cost or efficacy has been the prime factor determining the granting of licences for new drugs. Countries with no innovative drug indrusty have been more rigorous in granting new product licences particularly to the 'me too' drugs.

Norway is perhaps the best example of an advanced industrialised country where the drug regulators have really regulated the market. The Norwegian list of drugs contains less than 2000 dosage forms and strengths. There is no evidence than standards of health care delivery in Norway are in any way inferior to those in other countries of Western Europe where tens of thousands of drugs are marketed. Norwegian regulations specify that before any drug may be registered, the manufacturer must produce evidence of qualitiy, safety, efficacy, cost-effectiveness and need. The 'need clause' has led Norwegian authorities to reject applications for drugs already licenced in Britain, France or Germany on the grounds that no clear cut medical need has been demonstrated. Between 1975 and 1979, Norway refused more than half the applications made to its for licensing of new drugs[15]. It is sad to note that the 'need clause' which has made the Norwegian drug regulations a model to developing countries has, ironically, received a severe batering at the International Conference on the Rational Use of Drugs held in November 1985 in Nairobi and at the World Health Assembly held in May 1986.

Some countries have introduced measures to limit the number of drugs in the market and encourage rational use of drugs. These measure have taken three forms.

Firstly, countries which have a limited list of drugs in their national formularies and have strikt criteria for registering drugs. Norway and other Nordic countries have much fewer drugs than most Western European countries. Developing countries which have introduced limited lists of drugs and rationalised the use of drugs are Bangladesh, Chile, Cuba, Mozambique and Sri Lanka. Case studies and reports on the experiences of these countries have been published[15-20]. Unfortunately the goverments of Chile and Sri Lanka had reversed their rational drug policies due to pressure from vested interests and groups who opposed these policies[17-21]. China has recently introduced a list of essential drugs[22]. The list contains 278 drugs divided into 28 therapeutic categories.

Secondly, a two-tier system. Australia has prepared a limited list of essential drugs. These are supplied to patients at low cost while a large number of other drugs are available on a full cost basis[23]. A somewhat similar system operates in a large number of developing countries — the 98 mentioned in the UNICEF Annual Report for 1986 (See para 4). In all these countries, a limited list of drugs modelled on the guidelines prepared by the WHO is used in the public sector institutions. A much larger number of drugs are available in the private sector in these countries (Annex 1) the 'so-called programm of essential drugs' has not rationalised the pharmaceutical supply system in these countries. Evidence from these countries tend to support the findings of an Australian inquiry which concluded that a considerable problem of the

two-tier system is that the cost to patients increases by a substantially greater amount than the savings made by the Government.

Thirdly, some countries in Western Europe have introduced schemes to contain the escalating costs to national health services and health insurance schemes. The Department of Health an Social Services (DHSS) UK, has listed a number of drug formulations, particularly antacids and laxatives, which can be no longer be prescribed under the National Health Services. Federal Republic of Germany has introduced a negative list of drugs which may no longer be provided through health insurance for common, self-limiting illnesses.

B 4) Political will

'Medicine is a social science, and politics nothing but medicines on a large scale. – Rudolph Virchow –'

Both at the International Conference on the Rational Use of Drugs, Nairobi, November 1985 and at several World Health Assembly Meetings, the governments of all member states of WHO have accepted the concept of the rational use of drugs and the need for limiting the number of drugs in the market. The experience of Norway and other Scandivanian countries shows that limiting the number of drugs will not lower the standards of health care delivery. The experience of Bangladesh, Chile, Cuba, Mozambique and Sri Lanka[17-21] clearly demonstrates that the financial, technical and human resources available in developing countries are adequate to formulate and implement rational drug policies. Why is it that a large number of countries have not implemented such policies? Perhaps, the most important element necessary for accepting these policies, namely the political will, is absent in these countries.

It will be useful to examine what this 'Political Will' is, which is perhaps at the top of the list measures essential to guarantee the success of rational drug policies and rational use of drugs. The example of Chile and Sri Lanka show the close inter-relation between the existence/absence of political will and the success/failure of attempts to rationalise drug policies and drug use.

Chile underwent a major change of political will in 1964, when President Frei took over the government. (Sr. Frei later became a member of the Brandt Commission). In 1965 the government took measures to rationalise drug supply and use. In 1967 and national formulary with a limited list of drugs came into being perhaps the first of its kind in the world. In 1970, the general elections brought Dr. Allende to power. Rationalization of the pharmaceutical supply system continued. The next step was to organize centralised bulk procurement. The first international tender for raw materials was called in 1971. The industry struck back. In the three months following the call for the international tender, widely used drugs including analgesics, antibiotics, disappeared from the market. The manufacturers had cut down their production. They agreed to replenish the market within one week only when the international tenders were called off. The governments succumbed and forced to call off the tenders. This happened in 1972. By 1973, the government of Allende was toppled. The first essential drug programme that we know of, introduced in 1967 was dead in 1973, killed by the drug industry.

The Sri Lankan experience has some resemblance to the Chilian experiment. The forces that led to the reversal of the Sri Lankan reforms and the strategies they used have been well documented in a paper by Lall and Bibile[21]. This paper analyses the experience of Sri Lanka in reforming the structure of production, importation and distribution of pharmaceuticals, a sector dominated by transnational companies.

It traces the complex interplay of economic, political and ideological factors that affected the process of regulating transnationals and of establishing a State Pharmaceuticals Corporation, stressing the role of the medical profession in resisting reform and of political leadership in initiating and, later, retarding it. Sri Lanka's experience offers valuable lessons for understanding the transnational phenomenon in general, and the difficulties of reforming the pharmaceutical industry in particular; it also illustrates clearly the advantages that developing countries may gain from such reform.

Annex 1

Country	Percentage Share	
	Private Sector	Public Sector
Argentina[1]	93.7	6.3
Pakistan[2]	93.2	6.8
Thailand[3]	92.0	8.0
Indonesia[4]	91.3	8.7
Nepal[5]	90.9	9.1
Paraguay[1]	90.0	10.0
Philippines[3]	90.0	10.0
Bangladesh[4]	87.8	12.2
Singapore[3]	85.0	15.0
Belize[6]	83.0	17.0
Brazil[1]	80.0	20.0
Chile[1]	80.0	20.0
India[4]	80.0	20.0
Maldives[7]	80.0	20.0
Uruguay[1]	80.0	20.0
Trinidad and Tobago[6]	78.0	22.0
Mexico[1]	77.0	23.0
Barbados[6]	76.0	24.0
Peru[1]	75.0	25.0
Venezuela[1]	74.0	26.0
Grenada[6]	72.0	28.0
Saint Christopher-Nevis[6]	71.0	29.0
Colombia[1]	70.0	30.0
Costa Rica[1]	70.0	30.0
St. Vincent and the Grenadines[6]	64.0	36.0
Jamaica[6]	60.0	40.0
Malaysia[3]	60.0	40.0
Sri Lanka[4]	57.0	43.0
Antigua[6]	53.0	47.0
Burma[4]	51.6	48.4
Bolivia[1]	50.0	50.0
Dominica[6]	50.0	50.0
Montserrat[6]	47.0	53.0
Tanzania[6]	45.0	55.0
Ethiopia[9]	43.0	57.0
Saint Lucia[6]	42.0	58.0
Guyana[6]	35.0	65.0

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Workshop results in short:

Workshop 1:
From the passive patient to the active consumer

The discussion about the position of patients – in particular as drug users – in the health care system was heavily influenced by the experiences of patients who had to suffer from the detrimental effects of drugs. Their disputes with authorities and drug companies, their attempts to find out about who is responsible and who can provide them with independent information were the basis for demands which are summarized below:

With regard to detrimental effects of drugs the responsibility of pharmaceutical companies, the Federal Board of Health, doctors and pharmacists must be clearly regulated by law (which must be transparent and made public). If there is any well founded suspicion there must be a reversal of burden of proof as well as an adequate compensation. Moreover, independent drug licening committees (no representatives of the pharmaceutical industry) must be established and approval must be given only if there is a therapeutic advance (need clause). "Patients" must have a say in important bodies. A ban on drug advertising, the obligation to register all clinical studies (permitting a better evaluation of the substance presented for approval as well as later a better market control with the regard to any side-effects), and the registration of side-effects by an independent body should also be considered. Furthermore, industry's monopoly of information calls for a freedom of information act.

Patients should have the possibility to call upon independent information offices at a regional/local level, and a Federal Commissioner for the Protection of Patients (assisted by a team of experts from different fields) who should have controlling authority at the national level.

Under the heading "information and health" the importance of health education in kindergarten and at school as well as in voacational training (including the training for a job in the health sector) was stressed. The awareness of one's own bodyand its disorders should be raised and the problem of drug therapies should be discussed.

A main point of the discussion was the call for more, better and independent information relating to the package inserts and the discussion with the doctor. There is not only a need for an easier language (which still cannot be taken for granted) but also for an evaluation of the side-effects (benefit/risk relationship), for information on how side-effects can be recognized at an early stage and what should be done if they occur. Alternatives to pharmaceutical therapy should also be pointed out. The doctor is expected to give "comprehensive" treatment, i.e. to have enough time for the patient, to take him seriously, to listen to him, to have faith in the patient's feelings about the effects and side-effects of the drug, to explain alternatives and to admit the limits of the doctor's abilities. Last but not least there is a need for more information about the rights of patients and the help offered to assert their rights.

Workshop 2:
Assistance for the general practioner: Treatment schedules and sources of information

In the Federal Republic of Germany the discussion about structural reform centres around the idea of cost containment. At the same time, not enough attempts are made to improve medical care. The participants in the workshop agree that a discussion about any kind of lists must always bear in mind the benefit for the patient.

There is hardly any evidence for the use of **negative lists.** If these lists contain any non-essential drugs it would make more sense to remove these drugs from the market rather than to limit their use by drawing up lists.

The workshop primarily discussed the assessment of **positive lists** which are nothing new. Several countries, such as Belgium and the United Kingdom, have already developed complete formularies. Models of these lists for general practitioners presented to the workshop and developed independently of each other comprise about 150 active substances and are largely similar in content. It is obviously not so much a problem to produce positive lists on a scientific basis than to put them into practice. The positive lists which were presented must be voluntarily accepted by the doctor. Their acceptance and the actual impact on the selection of drugs need to be investigated.

Positive lists are not the "philosopher's stone" for the restructuring of a market flooded with drugs:

- Doctors must have better sources of information (more independent drug information)
- There is no need for advertisement and pseudo information provided by producers.
- Prospective doctors must be trained to be more critical.

Those who believe that "clinical freedom" will be restricted by positive lists obviously define "clinical freedom" as the freedom of therapists to use any drug or method without having to justify benefits ore risks of these measures. Positive lists make it easier for the doctor to select tested and effective drugs with an optimum benefit/risk relationship.

On the occasion of this workshop an initiative was launched with the aim to evaluate the existing positive lists and to compile a European positive list. Doctors in the Federal Republic of Germany are to use this list as a guideline in a drug jungle which has got out of control.

Workshop 3:
Working with hospital formularies

As long as there is no national licensing policy for drugs which is based on agreed criteria of use, risk and demand, therapeutically justified and limited drug formularies for hospitals (hospital formularies) are of great importance for a rational therapy. Drug committees should try to update the lists on a regular basis, i.e. therapeutically inappropriate drugs should be eliminated and useful innovations should be included.

How to compile such a list:

- Each department is asked to make suggestions for its specialty. Needs of special departments are taken into account.
- Already existing model lists can be used as a guideline.
- Changes of the list are published and justified.

These lists are mandatory.

For individual non-listed drugs a six-month appraisal period can be used in special cases. At the end of this period the inclusion of the appraised drug into the list must be scrutinized on the basis of a well founded request. The lists should be distributed to physicians as a source of information.

Other measures for the implementation of a rational drug therapy in hospitals

- In their discharge letters doctors are to use generic names instead of preparation names.
- The patients are already told in hospital that their family doctor might prescribe other preparations with the same ingredients.
- Hospital doctors are given lists contrasting preparation names with their generic ingredients.
- Drug samples are no longer accepted.
- As representatives of the pharmaceutical industry do not give any balanced and objective information there will be no more informative discussions. In future, they will have to direct themselves to the pharmacy management.
- Hospital formularies could be implemented more quickly because of the interest of hospital managements in cost containment. However, the well-founded medical decision must always have priority over mere cost factors.

Workshop 5 :
The international drug market

This workshop chaired by Professor Reich from the Centre for European Legal Policy at the University of Bremen benefited from the knowledge of the international panel. Gerardo Andamo, representative of Health Action Information Network in the Philippines reported on the deficiencies of the health care system in his country on the one hand and on the flourishing pharmaceutical industry making big profit on the other hand. Dr. Mira Shiva, representing the Voluntary Health Association of India, a network of 2000 health centres and initiatives in her country, said that the national problems arising on the drug market were actually international problems which needed to be solved at an international level. Promotion strategies and thus the influencing of prescribing habits and consumer behaviour are similar in the different countries. Dr. Chowdurhy from Bangladesh summarized it as follows: If pharmaceutical rubbish is available on the market there are always doctors who are willing to prescribe it.

There was a general agreement that ethic is indivisable and that, as Dr. Granitza from Schering put it, worldwide uniform supply should be strived for. He went on to say that the drug companies would have to assume responsibility for it even though there was often a gap between demands and reality. On the part of industry, however, the demand for uniformity was followed by a "but".

Then there was a controversial discussion about a limitation of the drug supply which was strongly advocated by all representatives from the Third World. Representatives of industry objected that this would prevent "innovation". According to Dr. Balasubramaniam this cannot be confirmed by experiences gained in Sri Lanka because a restricted drug policy continuously considers new findings in therapy rather than being static. However, the problem of monitoring side-effects of new substances, which as a rule cannot be guaranteed in thhe Third World, should not be underestimated.

A drug policy that limits itself to effective and essential drugs could even advance research. In this case it would only pay to de-

velop drugs which imply a real therapeutic advance and it would not pay for development of preparations that were primarily developed for reasons of marketing (patentability).

For the majority of the population it is obviously not so important to learn about the drugs of the future but to know that a restricted drug policy makes essential drugs cheaper and thus enables them to get access to "western medicine".

The discussion about the quality of drugs led to some surprising statements. Experiences from Bangladesh show that international companies quite frequently produce drugs of low quality which implies that this is not only a problem for domestic companies. With regard to quality there is much to be said for a limitation of the drug supply which is the prerequisite for effective control.

Drug information as an indispensable part of an effective therapy was seen as a major problem. Independent sources of information are hard to find in the Third World (and are often disregarded in industrialized countries). Since it cannot be expected in the short run that this is seen as a public task, independent information on drugs was regarded as an important task for initiatives and consumer organizations.

Workshop articles:

Prof. Borchert

From the passive patient to the active consumer

"The well-informed patient"—who is that? In my opinion this is someone who takes a drug only if it is really necessary and after he was thoroughly advised by the prescribing doctor and/or a pharmacist. He is someone who regards "health medicine" as a luxury good which should be taken as rarely as possible. If he falls ill of feels some pain he will first of all try to find out whether he can be cured by merely changing his way of life instead of having to swallow foreign substances.

How can prospective drug consumers inform themselves? The excellent drug test published by the Stiftung Warentest (Comparative Testing Foundation) in its periodical "Test", and the package inserts are some sources of information. In this context I would like to respond to Mrs. Müßeler's question: There have indeed been some studies in which consumers were asked to what extent they understand package inserts. Working at a university I supervise these relating to this question. When some pharmaceutical companies learned of these projects they hired one of my graduate students and paid him very well for this advise regarding a better wording of drug information. Thus, first steps have already been made in this direction.

I absolutely agree with the opinion that we can do without another source of information, i.e. drug promotion aimed at the consumer. Let me use this opportunity to do ome selfpromotion: One of my graduate students analysed TV commercials on drugs finding out that more than 50 % of these commercials violated established law.

What are the questions that consumers should ask their doctors? The most important question relates to alternatives to drugs that help the patient get well again or stay healthy. "How can we achieve an effective consumer information?" With regard to this question I must disagree with the otherwise excellent and very important film on Alival by Mr. Monheim because reports like this one automatically give rise to fears of drugs and this is certainly not the most appropriate way to raise the consumers' awareness and to achieve a more rational use of drugs.

How can the drug market become more transparent to the consumer and what should the legislator be requested to do in this respect? I think that this is not so much a question that needs to be answered by the legislator but a problem that needs to be tackled by other forces in society, i.e. consumer associations, organizations for the protection of patients, the media,etc. They have to see to it that more information will be given and that more transparency will be obtained. The publishing house Kiepenheuer & Witsch is one famous example which shows that it can work. However, I have not yet heard that there is a considerable decline in sales of drugs listed as hazardous drugs in the book "Bittere Pillen". This implies that a lot remains to be done with regard to further information.

What are doctors and pharmacists supposed to do? First of all doctors should learn to talk to the patient and to take him seriously both as a consumer and as a patient even though the patient obviously understands much less about this business than the doctor. Prospective doctors and practising doctors should learn to admit that they cannot help everybody who comes to them with a complaint. They must also be prepared to say: "The scientific methods that I have learned and that I know cannot solve this particular problem that you have at the moment (and this is why I cannot prescribe you a pill)." We call upon pharmacists to advise patients more. Experiences of consumers in pharmacies can be summarized by the title of a study published by the Stiftung Warentest: "Good advice is rare."

What do we expect of industry? I believe that if we are realistic we cannot expect too much of industry. Industry is necessarily committed to the logic of a capitalist economic system which will not be changed and perhaps does not have to be changed. If we fail to express the consumers' wishes and to organize information campaigns in a way that they have an impact on consumer behaviour industry will not change anything. If, however, consumers become more critical and do not want to buy drugs of a certain company anymore and if doctors do not want to prescribe these drugs anymore because they cannot accept the behaviour of this company, industry will be more willing to change things and consider the wishes of well-informed consumers. This is the challenge consumers must face. Let me give you an example: Those who take a pill in the morning to wake up and a vitamin preparation at noon and a sleeping pill at night should not only blame the pharmaceutical industry.

Let me briefly say something about the situational context. In my opinion it does not make sense, in particular in the drug field, to view the consumer only as someone who buys a certain product. We must also bear in mind that he is part of his social surroundings. Drug consumers are sick persons whose role is characterized by the fact that this sick person is released from the obligation to perform and that he is a burden to society because of the costs involved. He is almost forced to become passive and he is regarded as someone "under age". This cannot be changed in spite of all demands for a more rational health care scheme. In industrialized countries people tend to transfer their faith in technological progress to the medical sector and they believe that the health care system can be compared with a repair shop. This view can be found with everyone who suffers from complaints and who immediately asks the question: "What can be done about it?" This is also something that cannot really be changed.

Another new problem, at least in the Federal Republic of Germany, is the situation on the labour market. Everybody who can no longer fully perform must be afraid of losing his job if he has one. In our economic system these people are often rejected and this will lead to the situation that we all tend to ignore weakness or illness and that we regard drugs as a solution in an emergency. The drug market is a vehicle for the implementation and stabilization of social norms we all believe in. Unfortunately we will not be able to do something about the disadvantages in the near future.

Ingrid Schubert

Experiences with information centers for patients

The organizers of this conference asked me to report on the experiences that we have gained in the Patientenstelle ("Patient Agency") Munich as well as on questions that might be asked by drug consumers.

As to the Patient Agency Munich initiated in 1980 and financed by the Gesundheitsladen (Health Store) in Munich it must be stated that work had to be suspended because of the lack of financial resources for the payment of a full-time employee. By contrast, it is all the more encouraging that the Bielefeld health store succeeded in founding a patient agency.

Patient agencies are based on the idea of setting up independent agencies (i.e. independent of doctors, health insurance funds, hospital authorities) which can be addressed by everybody who has a question or problem which is related to health in its widest sense. Hardly anybody will deny that in their relation to providers of health services patients are in the weaker position although they are the ones who order the service. It is cynical to refer to the "mature patient" in this context (when actually calling upon the patient to retain part of the risk uninsured and to take over part of the responsibility without trying to find out about and change the conditions and causes of his much-complained immaturity.

Which questions were put to us by patients? They wanted to know about diagnoses and the course of a disease, about doctors ("Do you know a good doctor?") and about self-help groups, in brief, they were looking for independent, unbiased information. There were much fewer patients who sought legal advice: they came to get some advice on legal and medical facts when they suspected a doctor of having made a wrong diagnosis or of having given them the wrong treatment. The Patient Agency also had to deal with many problems of life, such as fears, addiction, partnerships crises, unemployment, loneliness. A Patient Agency does not only deal with problems of health care but also with social problems. When talking to patients we also learned about difficulties with health personnel but this was never the main reason for these people to visit our agency. Patients feel that they are not taken seriously, that doctors do not have enough time for them and disregard the subjective background of a disease. They told us about mistrust and the unwillingness to have a conversation. The deficits of health care which are often the reason for their complains are well-known: the schedule of fees, prescribing habits of doctors, hierarchical structures, the lack of cooperation between the different professions, the unwillingness to include all aspects in the treatment, lack of personnel and insufficient training.

The Patient Agency itself as an information body (e.g. on institutions and the services they provide, information on the patient's rights and, in particular, the right to ask questions and to see another doctor), as a clarification body (e.g. for patients who are not satisfied with the result of a certain treatment), as a mediation body (if a problem remains open the patient must often be referred to another institution; this must be seen as an individual field of activities), as an advisory advocate body defending the interests of patients (public officials, mass media – this is a field where we were not active enough).

One main concern of the Patient Agency has always been to encourage patients to put their questions to those who made them ask these questions, to support and enable them to talk to and debate with doctors. We were surprised to see that patients behave in a polite and respectful way even if they had bad experiences.

Patients rarely asked us questions concerning the use of drugs, which does not necessarily mean that they do not have any questions. So far, I have referred to patients of or visitors to our Patient Agency. I find it difficult to use the term "consumer" when thinking of drugs or pharmacies because this is where a product is sold and used some way or another (i.e. swallowed or thrown away).

Consumer protection and consumer interests in the field of drugs; this is a wide field ranging from legislative measures to individual behaviour. Let me address this very briefly: We must continue to demand the exclusion of industry from licensing committees, the ban on advertisement and the provision of samples and we must demand the setting up of an independent information agency for all these aspects have not been included in the amended drug law. Further demads must be made with regard to drug safety. This includes an efficient registration system of undesired effects. Such a system, however, can only be efficient if it also registers all clinical trials and uses their results in order to learn about certain risks at an early stage. As to the questions of a transparent drug market I feel that it is not enough to exert pressure from the bottom, to publish books like "Bittere Pillen". We have to make the fundamental decision whether everything that is developed must get on the market or whether a drug should be licensed only if it is a therapeutic advance on other drugs or on other methods. This also raises questions with regards to our research policy.

In discussions about drugs we continue to hear demands for intelligible package inserts. This is supposed to be taken into account by providing separate information for the layman and for the expert. I am not concerned about the wish for intelligibility but about the question who will decide what the customer is allowed to know (everything that does not keep him from taking the drug?). The production of intelligible texts does not only require the use of German therms but it must also include clear instructions and information on how to assess and indentify the listed risks. I have brought along the dissertation several package inserts in order to point out the linguistic tricks applied in the pharmaceutical sector. The listing of minor troubles and serious side-effects in one breath or confusing instructions such as "consult your doctor immediately" and "will pass" are only the more harmless examples.

In my opinion, drug information does not only imply more or better information but also the calling into question of the need for drugs. This requires a joint reflection (with others, with the doctor/Pharmacist) on why someone wishes to purchase a drug, what this person expects when taking this pill and how these expectations might be met by other means.

If it is necessary to purchase a drug the following aspects should

be taken into account (some might seem banal to you but pharmaceutical practice convinced me that these questions cannot be taken for granted):

1. Drugs are special products and therefore require explanations.
2. Pharmacies are business enterprises.
3. Do not swallow everything.

In addition to these phrases some other hints and questions are essential:

- Preparations with one active substance must be preferred to combination preparations unless the combination is pharmacologically useful.
- Be careful with new drugs. If a complaint is treated for the first time you should be treated with well-known drugs. Ask the doctor about his experiences.
- All the reactions of your body to a drug should be taken seriously, even if they are not mentioned in the package insert.
- Ask again if it is not clear what the preparation is for, what its effects are, how it must be taken, how you can identify undesired effects as early as possible, and whether you can stop taking the drug as soon as you feel better.

Dr. Gunter Hildisch

Demands on Basic Formularies (Positivlisten)

1. Price Comparison List (Preisvergleichsliste – PVL)

The PVL, a part of drug regulations, is to advise registered doctors on economical prescribing and therefore considers primarily economic aspects as can already be seen from the name of the list. The selection of the individual drugs in the different areas of indication was not only based on the price but also on quality aspects. This resulted in the scientific evaluation and classification of the drugs into three groups. In practice, however, the PVL turns out to be insufficient in many respects:

1. The PVL does not cover all areas of indication which are encountered in practice. Areas of indication which have not been listed are for example: gastro-intestinal drugs, urologic drugs, antibiotics, hormones, therapeutic agents for the liver, bronchi, and veins, anti-artery occlusion drugs, etc.
2. So far the 6-month-update promised in the foreword has not yet been produced.
3. There is no detailed information regarding the dosage of the individual drug specialties and there is a lack of information regarding unwanted effects and interactions.

This is why the PVL can only be regarded as a first step in the direction of a rational drug therapy. As long as the PVL has the above-mentioned shortcomings we cannot do without traditional drug lists. Therefore, in practice most doctors continue to use primarily the „Rote Liste" since they cannot yet do without this reference book.

2. Positive List

Based on the critical view of the several demands must be made on the drawing-up of a positive list which is meant for everyday use, which is interesting and which can be accepted and used by as many doctors as possible.

1. All common areas of indication must be covered.
2. The selection of drugs included in a positive list must be put on a scientific basis in consideration of economic aspects.
3. It must include treatment regimes for Chronic diseases (e.g. rheumatism, hypertension, etc.)
4. Detailed information concerning the dosage of the individual drugs should be given.
5. Unwanted effects and interactions with other drugs must be listed.
6. An update every six month to one year must be guaranteed.

If we succeed in drawing up a positive list which meets the above-mentioned criteria we might have a drug list at our disposal which on the one hand can be applied in practice and which on the other hand considers criteria of a rational and scientifically-based drug therapy.

Evaluation of a positive list based on practical experiences in internal medicine

The large number and variety of drugs sold on the West German market is certainly not needed and results in an unnecessary uncertainty with regard to transparency and drugs. On the one hand, the adoption and publication of the Price Comparison List in 1986 was a first attempt to make the drug market more transparent and to influence it by means of a recommended regulation. On the other hand, another list has been added to the already existing lists („Rote Liste", „Gelbe Liste"), and when in 1987 a special generic drugs list was published doctors had four lists for everyday use at their disposal.

This is why it seems to be useful to achieve further transparency of the drug market as well as of the lists by producing a binding „positive list". This list should not only be produced for economic reasons but also as a guideline for a scientifically based therapy.

This „positive lists" developed and regulary updated by pharmacologists, pharmacists and doctors should not be regarded as a restriction of clinical freedom but this selection of drugs on the basis of scientific knowledge is to lead to a better therapy and quality assurance.

A positive list should contain all active substances which according to present medical teachings are used for treatment in the respective areas of indication and which do not run counter to requirements in practice. The introduction of a „positive list" will neither lead to a lower quality of the drug supply nor to a leveling or standardization for there continue to be alternatives between the different drug specialities and formulations in the different areas of indication.

Moreover, it must be possible to prescribe drugs which are not listed in the „positive list" by giving individual reasons.

After the introduction of the list a transitional period should be granted in order to give prescribers enough time and possibilities to adjust theier therapy to the requirements of the positive list. In this respect they are supported by the scale of fees (EBM) because sub-paragraph 10 honours the discussion and planning of well-aimed therapeutic measures.

The positive list is meant to be guideline for a scientifically based and quality-oriented drug therapy taking primarily account of scientific and practical aspects and not necessarily of economic aspects only. In certain areas of indication more modern and more expensive drug therapies can be justified. Therefore, registered doctors as well as insurance companies must recognize the binding character of the list.

It must also be stressed that the daily therapeutic costs of a drug must be included in the „positive list" by taking an average daily dose as a basis because an econimic comparison between alternative methods of therapy can only be made on the basis of daily dosage costs.

The rapidly increasing number of generic drugs and suppliers of generic drugs results in an additional variety of approved drugs and we can even talk of the experience of two drug markets. The suppliers of generic drugs primarily point out the economic advantages of their preparations. However, the approval and inclusion of a drug in the positive list must not only be based on the price but primarily on the quality, i.e. bioequivalence, of the drug.

A regulary updated positive list could lead to a drug therapy independent of industry and based on pharmacological advice and it could prevent the routine prescription of unsafe and therapeutically inappropiate drugs. The introduction of a „positive list" might also involve some risks and disadvantages: Similar to the introduction of the „negative list" trivial cases are treated with highly potent drugs and this drug therapy might cause even greater damage because the positive list does not include drugs which are of therapeutic value becaue of their placebo effect and less because of active substances. This is why the positive list must not be seen as a restrictive element.

Basically, the prescriber still has the possibility to treat a patient in an individual and optimum way and – if necessary – to use a non-listed drug. This applies primarily to the field of phytotherapeutics and homoeopathic drugs. It must be made clear that a doctor can still apply alternative methods of treatment if he can give reasons in each individual case. In this respect there should not be too many demands on the prescriber.

Many doctors will certainly reject a "positive list" because they regard it as a restriction of clinical freedom. By contrast, it can be said that the "positive list" makes a contribution to more transparency and clearness on the drug market and that it does not represent an adminstrative selection of drugs but is based on scientific and practical findings of pharmacologists, pharmacists and doctors.

Even today the prescriber is influenced in this therapy by economic and adminstrative regulations and by the different kinds of drug promotion of the pharmaceutical industry. Insofar it can already be stated that freedom of therapy does not necessarily mean freedom of the therapist. If doctors learn to understand that the positive list is not a restrictive guideline but a source of information and advice I see no problems with regard to the use of the positive list in the future.

Dr. Marc Bouniton

Project ARCHIMEDE

ARCHIMEDE is a group of general practitioners and pharmacists interested by the promotion of the essential drug concept in the belgian frenchspeaking area in touch with **FARMAKA** in the dutchspeaking area.

We propose a essential drugs list for the family practice in Belgium as a way to improve the quality of the drug prescription. A smaller number of trusted drugs means health practitioners will become more familiar with both their desired effects and any side effects they may cause; following up the consequences of drug therapy will become more possible.

Our list includes 138 brand names, 11 vaccines and 31 preparations made by the pharmacist. One drug is selected for:

1) its effectiveness in relation with a real medical need.

2) the smallest possible number of side effects

3) its low price

4) its easiness to use (formulation, number of different forms,...)

We agree with the other conditions of the essential drug policy of the W.H.O. for the choice of the products (simple component, generic name if possible,...)

Two questions among others arise now in our experimentation:

– The place of the placebo?

– How this kind of list do resist in front of the symbolic attrition?

We are very interested by developing an essential drug list for primary health care at the european level before the beginning of the european market in 1992. This list could include DCI names only and could be very usefull for the political lobby at an international level in solidarity with the Third World.

Prof. Georges Peters

National drug policies: What has to be changed?

A change must be brought about in drug policy—just like in general politics—if the relation between the different social and political forces in a country has changed or changes in the near future. The forces influencing a drug market are on the one hand the suppliers, i.e. the pharmaceutical industry, drug wholesale trade and pharmacies (or drugstores) as ultimate sellers, and on the other hand the intermediaries and the consumers, i.e. doctors and health personnel, patients and ordinary citizens and finally the state with its health service. In Europe the relation between these forces has not changed in the last few years and is not likely to change in the near future. In the United States the newly elected Reagan Administration decided to interfere less and thus brought about a strong shift for the benefit of manufacturers and to the disadvantage of consumers. At the end of the Reagan era there will probably be a shift in the opposite direction. However, there must also be some changes in drug policies if states want to conclude treaties aiming at an adjustment of the different policies. Such an adjustment must be achieved in Europe where the Common Market will become a reality in 1992. As to a rational drug use there is, however, little hope that the EC drug policy will become more rational after 1992. The member countries of the European Community will probably agree on a policy of minimal inteference of the government. This will lead to the situation that in each country drug users must fight for their interests against the economically and politically superior suppliers.

In countries whose population has a certain influence on politics one might say that the citizens having the right to vote get the drug policy they deserve. A rational drug policy would most probably improve the health of people. Those who are convinced that this thesis is true are obliged to convince their fellow citizens.

In countries whose citizens have little influence on politics governments must be convinced of the benefits of a rational drug policy. This might be easier but for political reasons it is often much more difficult than a campaign with the directly concerned drug users.

To achieve a rational drug policy we should therefore not ask what must be changed but what would have to be changed in order to

... guarantee the supply of all people of a country with medically needed drugs.

... keep the expenditure on drugs in reasonable limits.

... protect patients and healthy persons from drug poisoning.

... reduce drug abuse.

1. Medically needed drugs

A relatively small number of drugs is available for the prevention (prophylaxis) of diseases: they are in particular vaccines, serums, disinfectants and some drugs used for the treatment of a disease (malaria prophylaxis, reumatism prophylaxis with penicillin, etc.) An even smaller number of drugs is used by doctors and clinicians for the identification of diseases (diagnostics). The overwhelming majority of drugs is used for the treatment of diseases. Here we must clearly distinguish between curative, palliative and symptomatic drugs. Unfortunately, many drug users and medical laymen do not know the fundamental difference between these groups: If, for example, someone takes drugs against fever and headaches when he has the flu, or if he takes drugs for the detumescence of the nasal mucous membrane and the desiccation of the dripping nose when he has a cold because he does not know that there are no curative drugs for influenza nor for a cold. Some physicians also do not know the exact difference between these three groups: There are quite a few doctors who believe that cardiac insufficiency can be cured with digitalis glycosides or that a nephrotic syndrome can be cured with corticosteroids and diuretics.

Curative drugs are drugs which are used over a limited period (for days or weeks, sometimes for months as in the case of tuberculosis or for years as in the case of leprosy) and cure a disease completely. Curative drugs exist only for diseases caused by microorganisms or parasites. It is possible, although unfortunately rare, that drugs can have a curative effect on cancer or leukaemia. Drugs eliminating a complication of a disease (such as coma in the case of diabetes or a crisis in the case of myxoedema or myasthenia) are no curative drugs because the patient remains under medical treatment.

Palliative drugs are drugs normalizing or considerably improving the sick patient's condition as long as they are taken. A number of palliative drugs replace hormones which have not been produced of carrier substances in the sick organism (insulin in the case of diabetes, liothyronine in the case of myxoedema and cretinism, levodopa in the case of Parkinson's disease). These drugs and vitamins lacking in the diet of individual persons or of groups and therefore given in the form of drugs (which happens rarely) are substitute palliative drugs. Other palliative drugs act on the organism in a way that it can continue to function quite normally in spite of the disease as long as the drugs are taken (Cardiac glycosides in the case of cardiac insufficiency, neostig-

mine in the case of myasthenia gravis, neuroleptics in the case of schizophrenia). Drugs transforming an normal condition into a desired abnormal condition as long as they are taken (oral contraceptives) are palliative drugs.

The vast majority of drugs used against diseases have a symptomatic effect, i. e. the repress an irritating symptom such as fever, tiredness, excitement, sleepiness, and, in particular, pain for the duration of action. The overwhelming majority of over-the-counter preparations have a symptomatic effect, if they have an effect at all.

Some drugs of these three groups are medically needed. In addition to these drugs however, other drugs are sold and taken which are medically not needed for the effect is solely based on the strong, superstitious or erroneous belief of the consumer (placebos). People also take drugs because they want to change their perception or consciousness in order to have pleasant dreams, to be heavenly peace or in a pleasant state of agitation. These active substances are called „recreational drugs" and sometimes they are referred to as „drugs" if they are banned or if society disapproves of them.

Relatively few drugs are needed to cover all efects that can be achieved with medication. Since 1980 the WHO has published a Model Formulary for Essential Drugs developed by different committees since 1977. These committees had been asked to produce a formulary of drugs that are necessary and sufficient in order to treat 95 % of conditions or symptoms which can be influenced by drugs. In 1980 this formulary contained 358 formulations of 249 pharmacologically active substances and in 1984 379 formulations of 262 substances. Since most symptoms are caused by frequently occuring diseases drugs listed in this Essential Drugs Formulary should meet the medical needs of far more than 95 % of all „patients". For the treatment of 99 % of symptoms and conditions responding to drugs certainly no more than 450 formulations of 350 pharmacologically active substances are needed. By contrast, more than 100.000 brand-name drugs are sold on the West German market compared with approximately 14.000 drugs sold on the Swiss market. Howeever, this glut of drugs contains „only" about 1.200 pharmacologically active substances. The large number of manufactured drugs on the market represents different formulations and an abundance of combinations of these 1.200 active substances.

By contrast, a good general practitioner "knows" about 30 drugs, i. e. he is informed about the effects, side-effects and the most important interactions with other drugs. A good specialist in internal medicine interested in drugs knows between 70 and 100 manufactered drugs. Unfortunately, doctors also prescribe drugs they do not really know. Of course consumers buying an OTC-drug usually do not know the drug at all. The percentage of these non-prescription drugs ist very high (in Switzerland they accont for about 45 % of the turnover achieved by pharmacies, in West Germany they make about 35 %). As a rule, neither doctors nor laymen are able to find out apparently different drugs sold under different names actually contain the same substances. In West Germany the generic name, i.e. the international acronym (INN or DCI) must be specified on the package. In Switzerland this information ist quite common but not obligatory. In contrast to the USA, however, generic names are indicted in small print and neither the doctor nor the consumer learn or find them when comparing different drugs.

As we have seen between 250 and no more than 350 different active substances are medically needed. This implies that the drugs sold in the rich countries contain 800—950 non-essential active substances include some traditional drugs used for many years although we hardly know anything about their real benefits or risks. The majority of drugs, however, are so-called "me-too preparations" or new active substances. Me-too preparations are drugs which a manufacturer puts and pushes on the market in order to replace and oust a drug with the same effects and of the same value produced by another manufacturer. New substances are often introduced by a manufacturer with the aim to replace one of this succesfull drugs whose patent protection has expired. This replacement serving mere financial purposes is justified by attributing the newer and more expensive active substances to mostly imaginary and advantageous properties. Many non-essential active substances are substances showing some potentially interesting effect in pharmacological trials without being of proven therapeutic value. Some non-essential active substances are not totally superfluous because they are useful for patients suffering from an uncommon disease or symptom. A much larger number of non-essential active substances is recommended against symptoms invented with the aim to promote sales: e. g. obscure vitamin definiciency syndromes such as spring fatigue, or restless legs, or premenstrual tension or the frequently diagnosed „larvate depressions".

The large number of drugs on the market which are unindentifiable or cannot be identified with absolute certainly leads to a large number of errors, confusion and mistakes when drugs are prescribed or purchased. Apart from the financial consequences many people take drugs which do not benefit them and whose (unavoidable) side-effects are detrimental to their health. Since doctors and the public are often insufficiently informed they often cannot recognize or avoid known side-effects or interactions. Uncertainty of the real composition of drugs is one reason why still unknown side-effects are not identified and why are they not reported in time to the registration bodies. Much too often a drug which is ineffective or not well tolerated is replaced by the same substance under a different name!

A rational drug therapy is the use of drugs which can prevent a disease or cure a disease, which, if a disease persists, can maintain an almost normal condition or repress a sympton, or which can improve the general physical and mental condition and which:

1. are taken in a minimal and effective dose
2. cause as few side-effects as possible
3. avoid unwanted interactions

and

4. can be purchased at the lowest possible price.

A fixed combination of two drugs can only be regarded as rational:

1. if the combination contains effeective doses of both drugs, and
2. if one of the two substances improves the therapeutic effect of the other substance or reduces or fights its side-effects, or if it prevents the risk of abuse of the other substances, and
3. if the combination has a better effect or fewer side-effects than a higher dose of one of the two components, and
4. if the combination contains two drugs which are frequently and justifiably prescribed and given to a large number of patients, and

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- it it can be proved that a fixed combination facilitates the regular use of the two components as directed.

The majority of single component preparations also do not contribute or contribute little to a rational drug therapy.

These facts result in demands for a rational national and international drug policy:

1. Drugs shall be licensed for sale only if their efficacy has been proved, if their likely effects outweigh the side-effects, if it is almost impossible to mix them up with other drugs and if a normally trained doctor can be have easy access to objective information on them.
2. Fixed-dose combination preparations shall be licensed only if they meet the above-mentioned criteria.
3. New drugs shall be licensed only if they have clear therapeutic advantages (better effect, fewer side-effects, fewer interactions) over drugs that are already on the market or if they have the same therapeutic effect but are offered at a much cheaper price. In this case license of the drug which is to be replaced by the new drug must be examined and perhaps revoked.
4. On all drug packages the international acronym (INN or DCI) of the main active substance(s) must be legible with the letters having at least half the size of the letters of the brand name.
5. All packages of OTC-preparations must be legibly labelled „Symptomaticum against ·..
6. All drug licenses must be examined at regular intervals of no more than five years by independent experts.
7. Public bodies must provide for obligatory further education of doctors in the field of pharmacology and pharmacotherapeutics.
8. Drugs which have not been licensed for sale in a particular country must not be exported to another country.

2. Public and private expenditure on drugs

Drugs are expensive and cost more and more money. It is often claimed that drug prices have increased less than the general cost of living in the last 10 to 20 years. However, this applies only to the few drugs which we used already 10 or 20 years ago. In the meantime the majority of drugs used at that time has been replaced by other and almost always more expensive drugs.

In Switzerland expenditure on drugs dispensed in pharmacies or by doctors (in the German part of Switzerland there are still some dispensing doctors) amounted to 1.454 million Swiss francs corresponding to 242 francs per person and year (13,9% of the overall expenditure on health amounting to 10.457 billion francs). When adding the expenditure on drugs dispensed in hospital pharmacies costs amount to 1.673 million francs in 1977 (16% of the overall expenditure on health) corresponding to 278 francs per person and year. In 1987, i.e. 10 years later, the percentage of expenditure on drugs dispensed in pharmacies dropped to 10.2% of the overall expenditure on health amounting to 19.600 billion francs (an increase of +87% in 10 years). However, the absolute expenditure on drugs dispensed in pharmacies increased to 1.999 million francs (by 37%9, i.e. to 333 francs per person and year. When considering the now more expensive drugs dispensed in hospital pharmacies expenditures make up 17% of the overall expenditure on health respectively 3.332 million francs, i.e. 555 francs per person and year. These are immensely high figures even though in 1987 overall expenditure on health in Switzerland accounted for only about 7.5% of the GNP compared with 11% in the USA but only 3,9% in the USSR.

Expenditures on drugs evidently include a big waste of money. If we assume optimistically that only a quarter of all prescribed and purchased drugs was inappropriate for treatment (false diagnosis, false prescription, misinterpretation of symptoms by laymen) drug expenditures could have been reduced by 25%. "Compliance" is the percentage of prescribed or purchased drugs which are actually taken. With large populations the mean "compliance" amounts to no more than 60%. This implies that 40% of drug expenditures are absolutely unnecessary. Finally, most doctors do not know that they continue to prescribe original preparations introduced by the initial manufacturer even when patent protection has already expired and equivalent so-called "me-too-preparations" are available which, in Switzerland, must be 25% cheaper than the original preparations if they are to be licensed by the health insurance funds. If we assume that half of the sold drugs could have been replaced by 25% cheaper me-too preparations 12% of drug expenditures could have been saved.

Table 1

Waste of money on drugs
Switzerland 1987: only expenditure on drugs dispensed in pharmacies and by doctors.

	%	country mio. francs	per person and year francs
Overall expediture	100	1,999	333.–
Waste due to:			
false indications	25	500	83.25
non-compliance	40	800	133.20
"original preparations" instead of "me-too-preparations"	12	250	41.60
Total waste	77	1,550	258.05

These reflectiones show that expenditure could be reduced considerably without anybody having to suffer. By avoiding detrimental effects of drugs people could be saved from harm. The percentage of drugs in overall expenditure on health is relatively low: it is lower than the expenditure on hospitals. Yet, drug expenditure are costs which could be substantially reduced by taking rational political measures. Savings would primarily benefit the citizen: in 1987 37% of overall expenditure on health in Switzerland was paid for by the public sector (taxes), 29% by Social Security and health insurances and 34% by private citizens or private insurances.

Worldwide the drug market is estimated to make up about $ 250 billion. This figure includes part of the sales within the chain of

drug supply. Suppose the public and the government spent $ 150 billion on drugs the world population of 5 billion people would spend $ 30 per person and year on drug needs. Yet, the large majority of the world population can spend less than $ 1 per person and year on drug needs. According to WHO estimates $ 15 per person and year would have to be spent in order to meet the need for essential drugs.

The price which consumers, their health insurance funds or governments have to pay for drugs is composed of the manufacturer's price and the trade margin. In Switzerland the manufacturer's price accounts for 56% of the final price with the overall trade margin making up 44% (see table 2).

Table 2

Break-down of drug prices (Switzerland 1984)

Manufacture (Expenditure on raw materials, machines, salaries amortization of investments):		22.4 %
Research and Development (including payments to other developers)		8.4 %
overall expenditure on promotion		13.4 %
(promotion with doctors	6.2 %	
expenditure on commercialization	5.0 %	
advertisements	2.2 %)	
Administration		6.2 %
Net profit		5.6 %
Manufacturer's price		5.6 %

The overall trade margin accounts for 44 % of the final price with 5.9 % going to the wholesale margin and 38.1 % to the trade margin of pharmacies.

Of the latter		
Wages (including income of the pharmacist)	account for	22.– %
Expenditure on business premises and amortization	account for	7.5 %
Other business expenditure	account for	5.1 %
Insurances	account for	3.5 %
Trade margin of pharmacies	account for	38.1 %
Wholesale margin	account for	5.9 %
Overall trade margin	account for	44.– %

This is why manufacturers can hardly justify their high prices with research expenditures accounting for only 8,4% of the final price compared with the expenditure on promotion amounting to 13,4%. In view of the pharmacist's role in drug preparation and dispensing their trade margin appears to be much too high. Today, pharmacists prepare few drugs only. Yet, they do other services to society by counselling, controlling prescriptions and by procuring drugs. Ideally, however, these services should not be remunerated via the drug price.

Within one country prices of the same drug sold under different brand-names can differ enormously: "me-too preparations" of the same composition can be 25% to 90% cheaper than original preparations and two original preparations manufactured by two different companies with the same active substance are not necessarily sold at the same price.

Prices of the same drug manufactured by the same company (often but not always under the same brand-name) differ even more in the different countries. In Spain and Italy, for instance, German and Swiss drugs are usually much cheaper than in the country of origin (-20 to -50%): this is why German bulk consumers reimport German drugs from Italy. In France, German and Swiss drugs are also often cheaper than in the country of origin (-10 to -30%).Why can pharmaceutical companies sell their preparations in other countries at a much cheaper price than in the country of origin and still make a profit? They are unlikely to renounce a profit or even to accept losses in the importing countries. This business would last for a few months only. If drugs were produced in the importing country by branches of the original manufacturer or on a commission basis by drug companies price differences could be explained with differences level. This explanation also seems to be highly unlikely because on the one hand price differences are usually higher than the differences in the wage level and because on the other hand pharmaceutical companies employ relatively few people due to highly advanced automation. The pharmaceutical industry, primarily the manufacturing industry, creates few jobs and needs relatively high capital investments. This fact is one of the reasons why the establishment of a pharmaceutical industry in developing countries is often a questionable undertaking.

High and to large extent avoidable costs are caused by the so-called advances in the drug sector, i.e. when new drugs having no substantial advantage over already existing drugs are developed. They are to oust a competitor from the market or to replace preparations whose patent protection has expired. "Of course" the new drugs are always more expensive and thus more profit-intensive than the old ones! In Switzerland, for example, from 1973-1983 every year 300-500 new drugs were registered. The majority of these newly registered drugs were new formulations or new combinations: every year no more than 20-40 new active substances were introduced. Out of these 20-40 new active substances only 2-8 drugs per year had therapeutic advantages over older preparation, i.e. they had better effects or fewer side-effects or had the same effect but were cheaper. This implies that 12-38 new active substances should not have been licensed at all!

This results in the following demands:

3. New drugs shall be licensed for sale only if they have clear therapeutic advantages over drugs that are already on the market or if they have the same therapeutic effect but are sold at a much cheaper price. In this case the license of the drug which is to be replaced by the new drug must be examined and perhaps revoked.

9. If a new drug is presented for approval the national drug registration authorities must have the right to examine and, if necessary, to reduce the price on the basis of the calculation of costs submitted by the manufacturer. Furthermore, the registration authority must be entitled to inspect the calculation of costs.

10. As soon as the patent protection has expired initial drug manufacturers shall no longer receive any price advantages when they are admitted to the health insurance funds.

11. The pharmacy's trade margin for drugs should be reduced. Pharmacists doing special services should be remunerated in

a different way.

12. As in some parts of the United States, pharmacists should be entitled to dispense a cheaper "me-too preparation" with the same components instead of the prescribed brand-name drug. Health insurance funds or their public supervisory authority could even oblige pharmacists to dispense always the cheapest preparation if drugs of the same composition are sold under different brand names at different prices.

13. Fixed combinations of drugs should always be labelled "combination preparation". It should no longer be allowed to promote new combinations or formulations of old active substances as a "novelty".

14. Unless there are important counter-arguments (in particular risk of abuse or of suicide) bulk packages lasting for the duration of treatment should be prescribed and sold. If drugs must be taken constantly packages lasting one to two months should be prescribed.

15. Doctors should take care that a patient does not take more than three drugs (exceptionally up to five drugs) at the same time. The patient should always be given written directions for use of all prescribed drugs. Doctors should regularly make sure that the prescribed drugs are really taken.

3. Drug poisoning

Usually this term is employed only for the consequences of drug overdosages. However, each effective drug has side-effects even if normal therapeutic doses are taken: there is no pharmacologically active substance which has only one effect on the organism. Yet, patients or prescribers almost always want to achieve only one effect. Therefore, all other effects of the drug are side-effects which, of course, are not always harmful. In practice, only those side-effects are important that are detrimental to the consumer's health or that could interfere with the effect of other drugs.

"Drug poisoning" refers to all side-effects of drugs which are detrimental to health and which are due to inherent toxicity. They are also many drugs which have a detrimental effect on those patients who have become oversensitive to a drug or to substances that are chemically similar to this drug: these effects are referred to as "drug allergies". It can happen with most drugs that occasionally people become oversensitive to them. The only important drug allergies are those occurring frequently when a certain drug is taken (e.g. penicillin-allergies) or those causing very dangerous allergic reactions.

As to the actual drug poisoning we should distinguish between poisoning caused by manifest overdosage (error, swallowing of tablets by small children, suicide attempts) and poisoning occuring with normal dosage. Drug overdosages as well as acute cases of poisoning must be treated (mostly clinically) with other toxic substances. Side-effects of drugs which occur with normal dosage must usually be diagnosed and treated by a doctor. However, this is only possible if the doctor had pointed out the symptoms of possible side-effects to the patient. There are also many drugs (in particular amongst analgesics and drugs against rheumatism) which, if taken once or for a short time, have few or no side-effects at all but which can have an extremly detrimental effect on health if used or abused for months or for years. The chronic toxicity of a large number of these drugs has only become known in the last 30 years. Since consumers have been informed about the possible chronic toxicity of drugs they often prefer so-called "mild" medicine produced from traditional plants ("phytotherapy") or "mild" drugs offered by therapeutic sects (homeopathy, anthroposophic drugs, sophrologic drugs, etc.). Many of these "mild drugs" have never been systematically examined for their chronic toxicity. This is why those replacing an effective but possibly chronically toxic drug by a mild "drug" exchange a known (and therefore avoidable) chronic toxicity for an unknown toxicity.

Before a new drug comes on the market different measures are taken to avoid side-effects. Some possible poisonous effects can be recognized in preliminary animal experiments. Other side-effects of drugs are recognized during clinical trials with a limited number of patients. Many side-effects, in particular those occuring more rarely are not recognized until a drug has been approved for sale and has been used by many people.

This results in the following demands:

16. Observations on possible side-effects of new drugs or combinations shall not only be reported to the manufacterer but also and in particular to the registration authority. Within the first five years doctors shall be obliged to report possible side-effects to the health authority in the same way as they are obliged to report certain infectious diseases.

17. Important or frequently occuring side-effects of prescription-only drugs must always be mentioned in package inserts, in brochures for doctors and in advertisements. Furthermore, package inserts must inform the consumer by listing and describing the symtoms pointing to the danger of a major side-effect.

18. Doctors should be given information about recommended therapeutic measures which must be taken in the case of overdosage.

19. The package inserts of OTC-preparations should always list the symptoms of possible side-effects and should inform the consumer which symptoms require the immediate treatment by a doctor.

20. Usually OTC-preparations are proven symptomatics which can be taken for a few days without any big danger. All packages of these drugs shall be labelled "Do not use for more than six successive days!".

21. These rules shall not only be applied to side-effects of drugs but also to the known consequences of interactions between different drugs or to interactions between drugs and other substances (food and surroundings).

4. Drug abuse

Patients, i.e. laymen, can abuse many drugs for different purposes. Many people take prescribed or non-prescribed drugs on a frequent or long-term basis in order to fight imaginary symptoms. There are just as many people who take ineffective and often non-prescribed drugs against their symptoms or desease. When several drugs have been prescribed dosages are often mixed up or misunderstood. Patients who have the impression that a particular prescribed drug helps them very often increase the doses or take this drug which has proved to be useful to them when they suffer from (another) new desease. Furthermore, drugs can be abused in order to commit suicide or to satisfy masochistic needs or to harm someone else.

Dependence-producing drugs are often used to fight withdrawal symptoms (laxatives, sleeping pills).

Yet, the most frequent abuse of drugs is certainly the use of psy-

chotropic drugs without any real medical indication, i.e. the abuse of drugs as "recreational substances". These substances are called "drugs" if their distribution is illegal, if society disapproves of them or if they are socially accepted but used excessively (alcohol, tobacco). Unfortunately, preparations dispensed in pharmacies (or drugstores) are always more acceptable than "drugs". Sleeping pills which are now often referred to as "anxiolytics" are therefore the alcohol and sometimes even the heroin of the good dutiful citizen. Analeptic amines (or ephedrine, or atropinoids) which have not yet been included in the Narcotics Law, and sometimes large quantities of coffee or chocolate are the law-abiding citizen's substitute for the analeptic amines of the black market ("speed") or for cocaine. After all, hallucinations cannot only be created with the illegal lysergide (LSD) or mescaline but people can also go on a "trip" with numerous legal drugs, beverages or tobacco.

Drugs used as "recreational substances" are particularly dangerous because they lead to dependence or, in the case of withdrawal, to a very unpleasant withdrawal syndrome. Such drugs are often referred to as "addictive". It is difficult to say whether this designation or the inclusion into the Narcotics Law can really limit abuse.

5. Summary

Drugs are often prescribed and even more often used in an irrational way. This is due to the chaos on the drug markets in the rich countries, the lack of an objektive continuous information of doctors and the public, the flooding of doctors and the public with propaganda material, the unconditional belief in the advantages of so-called new drugs, the underestimation of the risk of side-effects or interactions or other factors. Public and private expenditures on drugs are considerably higher than they would be if they met the medically justified needs. High drug prices are indirectly financed by the consumer via contributions to the health insurance fund or via taxes, and therefore the consumer notices them less than high food prices.

A better national drug policy could help to fight these grievances. 21 demands have been made to put such a policy into practice.

This text was not presented to the workshop in this way. Prof. Peters was so kind as to write an article on "National Drug Policy. What must be changed?" specially for this reader. Until then we had not received any contributions or results from Workshop 4. We should like to thank Prof. Peters for this additional work.

Drugs as Dregs

Do you have headache, fever, flu, cold, sore throat, muscle pain, or any pain in your body? The answer seems to be just a drugstore away. People have been made to believe that an illness can always be cured by a drug.

The drugstore with its bewildering array of drugs reinforces this belief. One is presented with shelf upon shelf of drugs of all kinds, colors and shapes. Pills, capsules, syrups, injectibles, ointments, powder – take your pick. Yet unknown to most people, many of these are unnecessary costly medicines we would be better off without.

Take the case of the medicines most people buy off the rack or over the counter.

Antibiotics are the largest selling drugs in the market, cornering 20 percent of total drug sales in 1984. [1] These antibiotics are important for the treatment of infectious diseases, common in developing countries where such diseases are aggravated by poverty, malnutrition, poor sanitation and poor housing conditions. Antibiotics are, however, widely abused. In 1984, 186 of the 241 antibiotics available in the Philippines were declared inessential by the World Health Organization (WHO). [2]

Antibiotics are commonly used in cases of diarrhea, a practice which is not only ineffective but harmful. A recent study revealed that 133 anti-diarrheal drugs registered with the Bureau of Food and Drugs (BFAD) contain antibiotics. Chlorostrep, Polymagma, Dostrol and Diazept (which were among the top eight largest selling anti-diarrheal drugs with total sales of P37.4 million in 1984) are of this kind. [3]

Cough and cold remedies are also top sellers, accounting for 11.6 percent of drug sales in the same year. [1] But the truth is, no drug has so far been found to prevent or reduce the duration of the common cold, a benign and self-limiting illness.

Of the 169 cough and cold preparations sold in the local market in 1984, 98 percent contained ingredients that have not been proven to be effective. The popular Vicks Vaporub is no exception. [2]

Other preparations combine ingredients that produce conflicting results. A common irrational combination is that of an expectorant, which induces coughing, and an suppressant, which suppresses coughing. In 1984, 64 cough and cold remedies were discovered to contain such irrational combinations. Neozep, Tuseran, Allerin, and Robitussin-AC are among the most popular brands of this type. [2]

Vitamins and general nutrients worth over P400 million were sold in 1984, a high price Filipinos pay for the modern quackery spread by drug companies.

Experts say that there are only a few valid uses of vitamin pills, and one of these is to correct defiency. Still vitamin preparations continue to proliferate. Today, one can choose from at least 186 vitamin and mineral preparations in the market. [4] But is this what majority of the people really need? Can vitamin pills take the place of basic nutrition?

Too, *analgesics or pain killers* have been making a killing in the drug market. There are more analgesics in the market than there are drugs considered essential (only six) by the (WHO). Drug companies distinguish their products from one another by combining two or more ingredients, although such combinations offer no real advantage. On the other hand, a popular analgesic like Paracetamol come in as many as 186 brands, and although they are similar in many respects, their prices differ markedly. [1]

Worse, brands containing the drug Dipyrone, which is banned in the US, Germany, Singapore and Japan, are widely used in the Philippines. The Philippine Index of Medical Specialties (PIMS) lists 17 brand names containing this banned drug. Among those in the list are Baralgin, Gardan and Gifaril.

Antibiotics, cough and cold remedies, vitamins and genereal nutrients and analgesics were the top selling drug products in the Philippines in 1984.

Expenditures on these drugs could, however, hardly be considered necessary. Indeed they highlight the irrational consumption of drugs. Why is it that billions of pesos are spent on such inessential drugs, while the majoritiy of our population are deprived of the essential drugs they so badly need?

The Need for Drug Regulation

It is estimated that 70 percent of drugs in the world market are inessential or dangerous. [1] This has given rise to a dangerous pattern of drug consumption both in developed and developing countries.

This has led governments to adopt an essential drugs program to protect consumers as well as to rationalize the drug situation. The WHO through its Essential Drugs Programme is in the forefront of this campaign. At the core of this campaign is the call for countries to adopt an Essential Drugs List (EDL).

The essential drugs concept is based on the idea that only a small number of drugs is necessary for most health problems; and these must be made available, in their proper amounts and dosage forms, at all times and to the majority of the population. [5]

If the WHO model list is followed, not more than 250 drugs are needed to maintain public health. Most of these are of single active ingredient, in contrast to the practice of drug companies of combining two or more ingredients to justify their brand names.

The WHO recommends that drugs be called by their generic rather than brand names. A generic name is the non-commercial name of a drug (also called its International Nonproprietary Name or INN) usually based on the scientific name of the active ingredient in the drug. Diazepam for instance, is the generic name of the tranquilizer Valium. Valium is the brand name given by Roche, the Swiss drug company which owns the patent for Diazepam.

The use of brand names is one of the major reasons behind the proliferation of drug products in the market. Drug companies market their own version of the drug with slight modifications.

Of the 9.838 registered drugs in the Philippines, 7,167 carry brand names. Acetaminophen or Paracetamol, an analgesic, is sold under 103 brands, singly or in combination with other drugs. Another favorite is Glyceryl Guaiacolate, an expectorant, which comes in 85 preparations. [4]

Government Intervention

President Aquino herself has come out strongly in favor of a more rational drug policy. In her speech before the Philippine Medical Association (PMA), she criticized drug companies for selling products of doubtful clinical value, a sign that „Science [is] losing to commerce everyday." She also urged doctors to free themselves from „pharmaceutical propaganda" and become „true medical scientists" instead. [Malaya, 22 May 1987]

Earlier, the President spelled out the four elements of a National Drug Policy (NDP): 1) strong Bureau of Food and Drugs (BFAD) to regulate the industry; 2) government participation in the procurement, production and distribution of drugs; 3) provision of adequate and objective information; and 4) coordination of investment and trade policies to achieve self-sufficiency in pharmaceuticals.

Last May 22, Malacanang came out with Executive Orders Nos. 173 and 174. The first is a welcome development because it strengthend the powers of the BFAD over the industry but the second merely amended the Food, Drugs and Cosmetics Act which by itself need not be strengthened.

The Task Force on Pharmaceuticals has yet to come up with its recommendations for an NDP. For over a year now, the task force has been mired in studies and consultations. Whether it will come up with more progressive drug policies remains to be seen.

As an antidote to the proliferation of inessential or harmful drugs aggressively promoted by drug companies, an EDL offers big benefits to developing countries like the Philippines. By serving as the basis for prioritizing production and importation of drugs, an EDL would save the country time and money wasted on unnecessary drugs.

At the same time, it could serve as the basis for developing the local drug industry. Through tax and credit incentives, the government could encourage companies to produce these essential drugs.

In 1983, in the face of a foreign exchange crisis, the Ministry (now Department) of Health, came up with a list of 220 drugs to be given priority in importation. Pressure from drug companies swelled the list to over 400 items. The list eventually came to naught. [1]

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The international drug market

Dr. Axel Granitza

1. The markets are different

The markets for pharmaceutical products in the various countries of the world are different. When roughly subdividing countries into
- developing countries
- industrializing countries and
- industrial countries

considerable differences arise already within these groups. Even industrial countries have considerable variations in the structure of their drug markets, which result from
- the different therapeutic and medical environment (as is generally known, there is no „world medicine"),
- the different doctor and patient habits,
- a different cultural, social and legal environment.

Medical sciences in Anglo-Saxon countries are, for instance, rather based on natural sciences, whereas they are understood as empirical sciences in Romanic countries. Both approaches, along with a broad range of medical opinions, are reflected by the German drug market and, for example, also by the provisions relating to the German marketing authorization (c.p. German Drug Law § 22, § 24 para 2, § 25 para 2, last sentence).

The following are examples of different drug consumption patterns in industrial countries:
- the significance of homeopathics and phytopharmaceuticals in Germany,
- the significance, for example, of drinking vials in France and Italy,
- the significance of syrups in the UK,
- the size of the antibiotic market, for instance in Spain and other Romanic countries as compared with other Western European countries,
- the significance of gastro-intestinal drugs, for instance in Japan.

The expert opinion for the concerted action in the German health sector[2] comments on this differences under item 205 as follows:

„In-depth studies have revealed, for instance, between (socially, scientifically, culturally) so similar Scandinavian countries like Denmark, Norway and Sweden considerable differences in prescription patterns of doctors and in particular also for drugs which may only be applied in the event of clearly defined clinical pictures (e.g.diabetes). A frequently mentioned example – which has already caused several misunderstandings – is the different treatment strategy in case of cardiac insufficiency in Germany (cardiac glycosides) and in Anglo-Saxon countries (diuret-

ics and saluretics)."

Item 207 of the same expert opinion reads as follows:

„Considerable differences on an international level result also from the breakdown of drug consumption by groups of indications. This can be illustrated by the following examples: An above average share of the indication „digestive tract and metabolism" in Italy and France, a high share of „central nervous system" in Belgium and Switzerland (below-average in Italy), a high share of „cardiovascular system" in the Federal Republic of Germany and Austria, low share, however, in the UK, in Switzerland and Spain."

When including developing countries in this survey, the differences of some selected markets – broken down by market segments – result from table 1.

Table 1: Leading indication groups in selected countries (industrial and developing countries)
Market shares in %, calculated on the basis of pharmacies' turnover, IMS 1986

Indication groups	Countries											
	FRG	F	GB	I	NL	S incl. hospitals	Japan	North-america	Indo-nesia	Korea	Pakistan	Philip-pines
Cardiac remedies	10.2	5.0	5.5	4.5	6.6	4.8	5.3	6.2	1.5	–	–	2.6
Plasma substitutes	–	–	–	–	–	5.4	6.0	–	–	2.7	–	–
Periphal vasodilators	6.2	–	–	–	–	–	–	–	–	–	–	–
Cytostatic agents	–	–	–	–	1.9	2.6	5.9	–	–	–	–	–
Antacids/ulcer healing drugs	4.2	3.2	8.0	7.0	5.9	4.8	5.7	5.9	3.1	5.7	3.0	2.7
Gastro-intestinal spasmolytics	–	–	–	–	–	–	–	–	–	–	–	–
Spasmolytics	–	–	–	–	–	–	–	–	–	–	–	–
Psycholeptics	4.0	4.6	2.4	–	4.9	4.9	2.2	5.0	1.9	–	2.2	–
Antidepressant drugs	–	2.7	1.8	2.2	–	–	1.7	2.3	–	–	–	–
Antitussives/cold remedies	3.9	3.7	2.0	4.6	2.5	–	–	3.0	6.7	9.6	4.9	12.0
Vitamins	–	–	–	–	–	–	5.6	–	7.5	9.0	8.5	7.5
Beta adrenoceptor blocking drugs	3.6	2.0	6.9	–	6.4	6.8	–	4.9	1.5	–	–	–
Diagnostic agents	–	–	–	–	–	–	2.0	–	–	–	–	–
Analgesics	3.3	4.4	5.8	2.7	3.3	5.6	–	6.3	4.9	4.0	6.3	5.6
Other cardiovascular drugs	–	–	–	2.9	–	–	–	–	–	–	–	–
Antihypertensive drugs	3.2	4.2	2.4	2.6	3.7	–	–	4.2	–	–	–	–
Vasoprotectors	3.2	5.1	–	–	–	–	–	–	–	–	–	–
Sera/gamma globulin	–	–	–	–	–	–	1.8	–	–	–	–	–
Sex hormones/stimulants	3.1	–	2.5	–	5.1	2.5	–	5.1	1.8	–	–	–
Ophthalmic preparations	–	1.9	–	–	–	2.5	–	3.2	1.5	1.4	2.1	–
Antirheumatic agents	3.1	3.3	10.2	4.3	5.3	3.8	2.7	5.7	2.0	2.1	4.1	–
Antirheumatic liniments	–	–	–	–	–	–	2.7	–	–	4.0	–	–
Systemic antibiotics	2.9	6.7	7.6	10.6	8.9	8.1	18.8	6.3	25.8	6.5	20.3	18.5
Vasotherapeutics	–	8.9	–	4.6	–	–	3.0	–	–	–	–	–
Diuretics	2.9	2.4	4.4	–	4.3	3.8	–	3.0	–	–	–	–
Anti-athmatics	2.8	–	7.7	–	6.1	4.9	2.2	2.8	2.1	–	–	3.1
Antidiabetic drugs	2.5	–	2.2	–	4.2	3.9	–	2.6	–	–	–	–
Other therapeutics	–	–	–	–	–	–	3.7	–	–	3.8	–	–
Dietary products	–	1.8	–	4.1	–	–	–	–	–	–	2.8	4.6
Corticosteroids, topical	–	–	1.8	–	–	–	–	–	4.0	2.1	1.7	1.8
Corticosteroids, systemic	–	–	–	–	–	–	–	–	2.0	–	–	1.7
Cholagogues/liver-protective drugs	–	–	–	3.6	–	–	–	–	–	4.7	–	–
Other CNS-stimulants	–	–	–	2.4	–	–	–	–	–	–	–	–
Other hormones	–	–	–	2.3	–	–	–	–	–	–	–	–
Immunomodulators	–	–	–	1.9	–	–	–	–	–	–	–	–
Anti-emetics	–	–	–	–	–	–	–	–	–	–	–	–
Laxatives	–	–	–	–	–	2.8	–	–	–	–	–	–
Tuberculostatics	–	–	–	–	–	–	–	–	2.4	–	4.0	4.1
Tonics	–	–	–	–	–	–	–	–	–	14.3	–	–
Digestants	–	–	–	–	–	–	–	–	–	4.4	–	–
Antihistamines	–	–	–	–	–	–	–	–	–	1.7	1.6	–
Antiparasitics	–	–	–	–	–	–	–	–	–	–	3.0	–
Antidiarrhoeal drugs/electrolytes	–	–	–	–	–	–	–	–	–	–	2.4	1.6
Antianaemic drugs	–	–	–	–	–	–	–	–	–	–	–	1.7
Percutaneous liniments	–	–	–	–	–	–	–	–	–	–	–	1.6
Appetite stimulants	–	–	–	–	–	–	–	–	–	–	–	1.6

A similar table entitled „Drug consumption in seven fields of indication in ten countries, quantified as defined daily dose (DDD) per 1.000 inhabitants per day[3]" had already been published by Friebel in 1982 (table 2).

Table 2: Drug consumption in seven fields of indication in ten countries, quantified as DDD * / 1,000 inhabitants / day

	Federal Republic of Germany (D)	France (F)	Sweden (S)	Denmark (DK)	Finland (SF)	United Kingdom (GB)	Norway (N)	Italy (I)	Spain (E)	Iceland (IS)
Psycholeptics	72,42 (1977)	85,32 (1977)	56,45 (1977)	87,38 (1976)	37,54 (1977)	77,79 (1977)	54,22 (1977)	44,70 (1979)	54,21 (1977)	59,88 (1979)
Cardiac glycosides	64,29 (1978)	8,81 (1978)	32,34 (1978)	10,50 (1976)	42,38 (1978)	10,16 (1978)	18,76 (1978)	16,65 (1978)	7,29 (1978)	8,39 (1978)
Antidiabetics	18,58 (1978)	13,26 (1978)	18,44 (1978)	7,94 (1976)	17,47 (1978)	7,56 (1978)	8,70 (1978)	11,55 (1978)	8,73 (1978)	4,17 (1979)
Antibiotics, systemic	5,43 (1979)	13,35 (1979)	9,76 (1979)	4,99 (1977)	10,31 (1979)	9,06 (1979)	6,94 (1979)	7,47 (1979)	8,73 –	11,27 (1979)
Antiepileptics	4,02 (1979)	7,52 (1979)	7,21 (1979)	5,27 –	3,45 (1977)	5,10 (1979)	6,42 (1979)	5,00 (1979)	5,78 (1979)	2,95 (1979)
Glucocoticoids, systemic	7,14 (1979)	7,46 (1979)	3,91 (1979)	(4,36) –	3,64 (1979)	1,57 (1979)	3,59 (1979)	6,04 (1979)	(4,36) –	1,50 (1979)
Sulphonamides, systemic	4,70 (1979)	2,58 (1979)	1,20 (1979)	3,64 (1977)	4,77 (1979)	2,57 (1979)	3,53 (1979)	6,05 (1979)	3,65 –	3,83 (1979)
* DDD = defined daily dose	Σ=176,58 (100%)	137,50 (77,9%)	129,31 (73,2%)	124,08 (70,3%)	119,55 (67,7%)	113,81 (64,5%)	102,16 (57,9%)	97,46 (55,2%)	92,75 (52,5%)	91,99 (52,1%)

The multinational pharmaceutical companies are therefore not operating on a homogeneous international market, but have to adapt to strongly different structures.

A large number of drug suppliers is primarily operating on an national market, for instance exclusively on the German market, or covers only few selected markets. Such companies have in most cases another cost structure than researching companies.

Researching companies are interested in exploiting the results of their research activities as far as possible on a worldwide level in order to optimally amortize their research costs. The most cost-effective way for them would be to equally supply their product range worldwide, i.e. without variance with worldwide uniform statements and at worldwide uniform cost-covering prices. This would not only be rational, but such a behaviour would certainly also give rise to less criticism.

Realities, however, are different. Diverging medical doctrines and different consumer habits, which the pharmaceutical companies need to take into account, can possibly also result in a commercially different status of a drug in the various countries. Moreover, they result in differentiated considerations on drug safety (risk-benefit assessments have also a regional component[4]), for instance because of different availabilities of alternative therapies in the respective countries or because of diverging evaluations of facts in risk-benefit-assessments. Each assessment – which is, for instance, carried out by public authorities – has political elements which can, of course, have regionally different emphasis[5]. This does not mean that every serious manufacturer must not set for himself the standard to distribute in no country of the world drugs which are unsafe in medical terms; since such a safety evaluation has primarily a global character, the global assessment must precede the regional evaluation.

When such a safety evaluation is, however, not at issue there is, of course, no pressure to behave in a uniform way.

Consequently, there is no indication of a tendency towards homogeneous markets in the pharmaceutical industry. Some good arguments stand in the way of a global marketing of drugs, a trend which exists also for many other industrial products.

2. A uniformization of markets by lists is not possible

The different regional structures described above, and the different therapeutic environments set bounds to a uniformization of markets by drug lists.

The list of so called Essential Drugs of WHO represents a model to select the most urgently needed drugs which should be available to cover the needs of the population of developing countries whose basic requirements cannot be covered by existing drug supply systems. This list is thus to assist developing countries in elaborating their own drug policy adapted to national conditions and needs. With this list WHO does not at all have the intention to limit drug supplies of developing countries or even industrial countries to the drugs contained in that list; drugs which are not included in the list are thus neither considered as superfluous or dangerous, nor is their therapeutic benefit questioned.

This is confirmed by the following quotation from „The use of essential drugs" (Second Report of the WHO Expert Committee, WHO Geneva/1985 – Fourth Revision of the Model List of Essential Drugs, page 6):

„In undertaking a further review of the list, the present Expert Committee has throughout been guided by the following statement contained in the previous reports:

Because of the great differences between countries, the preparation of a drug list of uniform, general applicability and acceptability is not feasible or possible. Therefore, each country has the direct responsibility of evaluating and adopting a list of essential drugs, according to its own policy in the field of health.

The list of essential drugs based on the guidelines put forward in this report is a model which can furnish a basis for countries to identify their own priorities and to make their own selection.

The Committee also draws attention to the following guidelines set out in the initial report:

(1) The extent to which countries implement schemes or establish lists of essential drugs is a national policy decision of each country.

(2) As far as health services in developing countries are con-

correct, the essential procurement and use of essential drugs have many advantages in terms of economy and effectiveness. However, the concept of „essential drug lists" must accomodate a variety of local situations if the lists are ever to meet the real health needs of the majority of the population....
(4) Such „guiding" or „model" lists should be understood as a tentative identification of a „common core" of basic needs which has universal relevance and applicability. The further local needs move away from the core, the more the health authorities or specific sectors of the health services will have to adjust the lists. Therefore, any list proposed by WHO should set out to indicate priorities in drug needs, with the full understanding that exclusion does not imply rejection. A list of essential drugs does not imply that no other drugs are usefull, but simply that in a given situation these drugs are the most needed for the health care of the majority of the population and, therefore, should be available at all times in adequate amounts and in the proper dosage forms."

This already clearly shows that the Essential Drug List of WHO cannot claim to worldwide validity.

The Essential Drug List deals with basic medical supplies and does not take differentiated clinical pictures or the subjective disease perception prevailing in developed countries into due account. A large number of diseases caused by civilization does not exist in developing countries or does not exist in the same form as in industrial countries.

As for the rest, the Essential Drug List is a list of active ingredients and not of finished drugs. Consequently, it can in the existing form hardly serve as a guideline for prescription patterns.

But also when using the Essential Drug List or another list exclusively in all population groups of one single developing country, e.g. also in the better-off middle and upper classes for instance in the capital of this country, the therapeutical needs prevailing in this population group would hardly be satisfied[6].

All the more, there can be no lists applying uniformly to several countries. We currently experience that in the European Communities, whose drug laws are largely harmonized, the mutual recognition of marketing authorizations is in the final analysis prevented by the different medical doctrines in the EC-member countries, which render a uniform EC-wide risk-benefit-assessment difficult. A list-determined, uniform drug treasure is currently unimaginable in the EC.

Each country should, moreover, beware of an unreflected transfer of its own scientific opinions to other countries.

There are not only objections to a countrywise approximation by lists, but also to countrywise different, but centralized lists in each country, for instance in the sense of positive lists for industrial countries such as Germany, for the following reasons (see item[3].

3. Even if lists could standardize the markets of a country, such a unifomization would not be desireable

Several reasons speak against a uniformization within a country:

- market within the meaning of the heading of this paper implies the free development of competitive forces on the supply and demand sides. Market means competition, i.e. also competition between different drug suppliers. A list which does not permit this competition or restricts it, which excludes or selectively includes, is anit-competitive.
- Central decisions – as documented by a list – cement supply monopolies, because they are unflexible. Central lists would have to be constantly updated. The cementation of monopolies involve the risk of an even higher concentration of the pharmaceutical industry.
- The decentralized decision of doctors when prescribing drugs ist more appropriate to contribute to the optimization of drug supplies than centralized decisions. There should be concern about the tutelage of doctors and patients, about the „advice of the wise", about central control. This involves the risk of arbitrary decisions. There is, however, one exception: only the central decision of the approval authorities, which is determined by the interests of drug safety, is acceptable; this does, however, only apply if it sets merely a frame for doctors and patients to guide concrete drug safety decisions.
- Drug lists, which result in a constant number of prescribable drugs, do not lower drug consumption. In the already mentioned expert opinion for the concerted action in the health sector, it is pointed out that the drug expenditures, e.g. in France – with a lower number of drugs – are higher than in the Federal Republic of Germany.

Other sources likewise show that there is no relation between the per capita drug consumption and the number of drugs available on the market in the European countries, as can be seen from table 3.

Table 3

Country	per capita consumption in single doses for the years 1985 + 1980 *	number of specialities	number of presentations
1. France	1,640	4,200	8,300
2. Italy	1,557	5,926	12,128
3. UK	1,431	2,336 (without OTC)	10,322
4. Spain	1,297 *	6,500	13,620
5. Belgium/ Luxembourg	1,203	2,412	6,353
6. Switzerland	1,138	8,500	10,000
7. Federal Republic of Germany	997	8,882	11,086
8. Austria	853	–	6,543

Source: BPI Pharma Daten 87, page 42 and EFPIA Statistics 1984

Friebel comments on this as follows[7]:

„The question whether the size of the drug supplies has a major impact on the consumption volume and the consumption profiles cannot be exactly answered. Data available from Nordic countries do not show such a relationship."

WHO has likewise stated that there is no relationship between the number of drugs and the volume of per capita consumption[8].

As far as the number of drugs is concerned, the following should be added in this connection:

About 88 % of the drug consumption in Germany falls to the share of some 2.000 drugs[9].

It should also be taken into account that the Rote Liste covers 8.792 product entries and 11.101 presentations, and represents

95 % of the drug production in the Federal Republic of Germany[10].

- Central lists with cemented monopolies and market structures are often anti-innovative and anti-progressive. They involve the danger of decoupling from progress in the drug therapy. Progress frequently occurs in small steps, in small thresholds which are in most cases not important enough for access to a list. Lists must be constantly updated, which is in practice hardly the case (example: the long revision intervals of the PRONTUARIO in Italy). Innovative companies can as a rule not rely on lists. The classification of new products in the extended price comparison list is a good example for this. Add to this that frequently a written or unwritten criterion for access to a list is the price. For that reason new, higher priced products have frequently lower chances.
  Finally, researching companies must often take long development periods into account; for that reason the environment must be foreseeable for a longer period. If a researching company can no longer be sure that, for instance, a drug developed with an expenditure of DM 250 millions will get the blessing of a commission deciding on the entry into a list, research will be seriously hampered.
- Central decisions do not take due account of medical science as (also) an empirical science, because they do not consider the individual experiences of the individual doctor. In the expert opinion on the concerted action in the health sector, item 198 comments on this as follows:
  „The doctor decides on the indication of a pharmaceutical therapy on the basis of his professional expert opinion based on the requirements in the individual case. The considerable differences with regard to the use of drugs are resulting from the described double function of the drug as a psychological aid of medical treatment and as a substance with a clearly proveable pharmacological effect in the most favourable case. Depending on personal experience, the typical national medical doctrine and the age and state of education of the doctor, drug prescription can be different for one and the same diagnosis. In medicine, there are only few situations which allow only one possible approach."

Central decisions must be based on an average patient who does not exist in reality. Different costitutional conditions, metabolisms, age, state of disease, deserve differentiated treatment possibilities. The fitting key for the respective lock must be found; an individual, concrete risk-benefit-assessment must be carried out; the patient is an emancipated citizen with a claim to individuality, he is not the object of a pre-established list. The adequacy of a drug prescription does not primarily depend on conformity with an average and abstract doctrine, but will be decisively determined by the risk-benefit-assessments in the individual case.

- Central decisions promote uncontrolled substitution processes (this results already from the experiences with the negative list in Germany). This risk is inherent in positive and negative lists.
  Besides adverse substitution processes, e.g. the use of potent drugs where weaker ones would be more appropriate, the risk of uncontrolled establishment of black markets or uncontrolled import activities should be taken into account[11]. The great number of individual recipes in Norway, a country with a very low number of drugs, shows this tendency towards substitution processes.
- Central decisions in respect of the establishment of a list are not only the result of drug safety considerations. Also terms such as „better than", „useful", „less useful", „need" are as a rule decision criteria for the establishment of such lists. These criteria are hardly objectifiable. Drug safety oriented risk-benefit-decisions are already based on an evaluating global consideration of a drug, founded on a great number of facts, such as data to substantiate efficacy, the severity of side effects and their frequency etc. These date cannot be compared with one another in an abstract, objective way. A global evaluation based on such assessments of different data is likewise hardly rationally understandable. And it is even more difficult to rationally substantiate an evaluation such as „better than" or „more progressive" or „there is a need". This rather involves the danger that arbitrariness is disguised into alleged rationality.

What should be achieved instead of uniform lists, or what is desireable?

The transparency of drug supplies to promote decentral decisions is necessary and desireable. The pharmaceutical industry has already for al long time contributed to the discussion on transparency (e.g. by intense cooperation in the German Tranparency Commission).

Rational therapy involves i.a.: Doing the necessary, doing without the avoidable, not to take a steamroller to crack a nut. This involves medical behaviours and not something which can be abstractly included into a list. It is necessary to influence medical behaviours or to educate and promote „correct" behaviour (e.g. by postgraduate medical education, for instance in the field of pharmacology).

„Ratio" is neither suited for uniformization nor an export article. On the pretext of rational therapy, we should not exercise a tutelage on other countries, but with the help of „ratio" we should contribute towards promoting their self-responsibility.
Moreover, it is necessary to promote the „proper" or „rational" use of drugs by the patients. And it is necessary to promote in developing countries the infrastructure of the health sector in order to actually allow such a „proper" use of drugs.

Lists are useful if they are the result of decentral – and thus not arbitrary – individual decisions. There is nothing to be objected to the fact that a hospital (in my opinion not an association of hospitals) or a doctor establishes, updates and revises a list containing drugs that they can use or want to use. Such an inofficial list certainly exists in each doctor's practise. More than several hundred products are not likely to be frequently included in such a list.

It goes without saying that the lists of each doctor are completely different – depending on his assessment and discipline. A pulmonary specialist has another list than an orthopaedic specialist. Individual lists are easier to handle and avoid the above mentioned disadvantages.

1) Excerpts from this statement were presented in a panel discussion in Bielefeld on 17 October 1987 within the framework of a congress organized by BUKO (pharma campaign): „Fewer drugs – better therapy. Learning from the Third World?"
2) Annual expert opinion 1987 „Medical and economic orientation", Nomos Verlagsgesellschaft (Baden-Baden 1987)
3) Friebel „Arzneimittelverbrauch" in Deutsche Apothekerzeitung No 15 of 15.04.1982, page 816.

4) cp. Füllgraf „Arzneimittelgesetz – Anspruch und Wirklichkeit" in Pharm.Ind. 42, No 6 (1980), page 581 ff

5) cp. Granitza „Tendenzen und Probleme bei der Erstellung von Arzneimittelinformationen in einer multinationalen Gesellschaft" in Pharm.Ind. 42, No 1 (1983), page 34 ff

6) The Association of the Local Pharmaceutical Industry in Latin America is right to warn against such a non-differentiated approach, SCRIP of 21.08.1987, page 18

7) Deutsche Apotheker Zeitung No 46 of 15.11.1984, page 2393

8) Pharma-Argumente, September 1986, page 11, item 6

9) Pharma-Daten 1987, published in August 1987, page 32

10) Pharma Jahresbericht 1986/1987, state: 1 May 1987, page 27

11) Oppermann: Die „neue" Arzneimittelpolitik in Bangladesh: Ziel verfehlt – Pharm.Ind. 47, No 11 (1985), page 1164

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Press reports

West Germany

FEWER DRUGS, BETTER THERAPY: LEARNING FROM THE THIRD WORLD

IN mid-October a new kind of international conference took place in Bielefeld. It was convened by BUKO, a coalition of about 200 German development aid groups, which had since 1980 been campaigning for more responsible marketing of drugs in the Third World and at home. The aim was to highlight a fundamentally similar irrational use of medicines in many developing and industrialised countries.

For instance, both in West Germany and in India well over 40 000 different formulations are on the market. At the other end of the scale are Norway and Mozambique, with less than 3000 formulations. The WHO model list of essential drugs contains only about 250. The conference discussed the relationship between such numbers and the quality of drug use. Of the 50 top-selling drugs in Germany in 1981, 6 were medically unjustifiable combination products, and 10 were of unproven efficacy—for example, cerebral vasodilators. In India, where drugs are used with fewer safeguards, the risks to patients are much more serious. Most drugs that in theory require a prescription can be and are sold over the counter by untrained people; the illiteracy rate is high, and only 2% of the population can read English, the main language for drug information.

Dr Mira Shiva, coordinator of the All India Drug Action Network, cited India as an example of a country with a well-developed pharmaceutical industry—9000 manufacturing units producing 60 000 formulations—which is no way to meet people's health needs because there is no rational drug policy. Despite the recommendation of the official Hathi committee in 1975, India still has no essential drugs list. Perhaps because the Department of Chemicals and Petrochemicals in the Ministry for Industry is responsible for drug policy, the concept of essentiality has been confused and confounded with issues of pricing and industrial development. The Hathi report was nevertheless unexpectedly influential in that it inspired the creation of the successful Bangladesh drug policy—described at the meeting by Dr Zafrullah Chowdhury. In India drugs not only cost more than in Bangladesh, but 60% or more of the preparations sold are irrational, hazardous, or non-essential. The huge number of formulations makes it impossible to maintain good manufacturing practices and adequate quality control, even though India has 6 quality control laboratories and 600 drug inspectors. The result is that about 20% of drug products sold are pharmaceutically substandard. Efficient price regulation for so many products is also impossible. The pressure of the present debt crisis on the health and education budgets makes the adoption of an essential drug policy more urgent than ever in all developing countries.

These examples illustrate the many interconnected problems in the way medicines are regarded and used in different societies—such as absence of coherent national drug policies, deficiencies in the laws governing medicines and in their enforcement, lack of reliable information for prescribers and users, and unrealistically high expectations from medicines, not least the result of commercial promotion. The problems are daunting and will take a long time to solve, but, the conference suggested, progress in tackling even one link in the chain could, by changing the conditions of drug use, bring about improvements in others.

An obvious approach epitomised by the essential-drug concept is to reduce the number of drugs in use. This can be done in a variety of ways: by enforcing high standards of proof of efficacy and safety before licensing a drug; by requiring it to meet a medical or economic need, as in Norway; by statute—for example, the Bangladesh Drug Ordinance; by restricting the range of drugs paid for from health insurance funds, as in many industrialised countries; by distributing positive lists of recommended drugs and tabular "transparency" lists, which facilitate comparisons between similar products; and by developing selective drug formularies.

Two of the workshops at the conference discussed how formularies can be created and maintained in hospitals and in general practice. In Germany very little such work has been done, and some of the young doctors and pharmacists at the conference welcomed the encouragement and help offered by, for example, Dr Joe Collier (St George's Hospital, London) and Dr George Grant (department of general practice, University of Newcastle); they were keen to get started themselves. Many German hospitals have a drug list, but in most cases it is merely compiled by the chief pharmacist to meet the demands of the medical staff without discussing the underlying rationale.

The conference gained a valuable extra dimension from an industrial view presented by Mr G. Lewandowski, a senior member of the pharmaceutical policy department at Ciba-Geigy, who had been vice-president of the German Federal Health Office (BGA). He said that a rational drug policy could be developed only through constructive dialogue between all those concerned, including not only pharmacologists, clinicians, industry, and government but also consumers, patients, politicians, the media, and public-interest groups. A drug might be defined as a substance plus information, and the quality of the information was critically important for rational drug use. A poor information policy could be as dangerous as harmful and obsolete drugs. Misbehaviour becomes very expensive for companies. Greater transparency should be achieved by making companies' data of efficacy, safety, and drug utilisation accessible to doctors and patients. Many individuals within companies were seeking higher standards. It would be wise for companies in their own interest to adopt higher standards than those set by industry or trade associations, which in their nature defend the status quo.

Mr Lewandowski's refreshing approach contrasted sharply with that of two representatives of Hoechst, who appeared unable to say convincingly in what ways the company had improved its internal decision-making in the wake of the traumatic experiences with nomifensine and dipyrone.

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PHILIPPA SAUNDERS

The Lancet, Nov 7, 1987

Fewer drugs, better therapy?

Remarks made by Günter Lewandowski of Ciba-Geigy at the recent BUKO meeting on "Fewer drugs, better therapy: learning from the third world" were greeted with approval by consumer representatives at the meeting. Philippa Saunders of Oxfam, in her report of the meeting which was published in The Lancet (November 7th), welcomed Mr Lewandowski's view that a poor drug information policy could be as dangerous as harmful and obsolete drugs.

Mr Lewandowski, who was previously with the West German BGA and is now with Ciba-Geigy's pharma policy department, commented that a drug may be defined as a substance plus information and the quality of the information was critically important for rational drug use. His acknowledgment that misbehaviour could be very expensive for companies, and that greater transparency could be achieved by making companies' safety, efficacy, and drug use data accessible to doctors and patients are highlighted in Ms Saunders' report. She also notes his comments that many individuals within pharmaceutical companies were seeking to achieve higher standards and that it would be wise for companies, in their own interest, to adopt higher standards than those set by industry or trade associations, which by their nature "defend the status quo".

"Mr Lewandowski's refreshing approach contrasted sharply with that of two representatives of Hoechst, who appeared unable to say convincingly in what ways the company had improved its decision-making in the wake of the traumatic experiences with nomifensine and dipyrone", Ms Saunders declares.

Participants at the meeting commented on the differences between countries like West Germany and India, where over 40,000 different formulations are on the market, and Norway and Mozambique, which have fewer than 3,000 formulations,

and discussed the relationship between such numbers and the quality of drug use, Ms Saunders notes. It was concluded that, in India, where it was said that drugs were used with fewer safeguards than, say West Germany, the risks to patients were "much more serious".

India was cited by Dr Mira Shiva of the All India Drug Action Network as an example of a country which had an urgent need of an essential drugs list. Prescription drugs are widely available over the counter, the illiteracy rate is high, and only 2% of the population can read English, the main language for drug information, the meeting was told. Dr Shiva observed that India had a well-developed pharmaceutical industry, with 9,000 manufacturing units, producing 60,000 formulations, but with "no rational drug policy". Despite the recommendations of the Hathi Committee in 1975, India still does not have an essential drugs list, she said.

Ms Saunders' report notes Dr Shiva's speculation that, perhaps because the Department of Chemicals and Petrochemicals in the Ministry for Industry is responsible for drug policy, "the concept of essentiality has been confused and confounded with issues of pricing and industrial development". It was alleged that in India 60% or more of the pharmaceutical preparations sold were "irrational, hazardous, or non-essential", about 20% were substandard, and that efficient price regulation was impossible. It was also noted that the Hathi report had inspired the Bangladesh New Drug Policy, which was outlined at the meeting by Dr Zafrullah Chowdhury of Gonoshasthaya Kendra.

The problems involved in achieving rational drug use are described by Ms Saunders as "daunting" but, she adds, as the conference suggested, progress in tackling even one link in the chain, ie by changing the conditions of drug use, could help bring about improvements in others.

An obvious approach, Ms Saunders suggests in the Lancet report, would be to reduce the number of drugs in use, for example by: enforcing high standards of proof of efficacy and safety; requiring evidence of economic or therapeutic need; making essential drugs lists mandatory; restricting reimbursement; distributing "transparency" lists; or by developing selective drug formularies. Various speakers at the meeting outlined some of these alternatives, which were also discussed in workshops — Dr Gadeholt of Oslo University spoke about the Norwegian need clause; an AOK speaker, Dr Gerd Glaeske, discussed positive/transparency lists; Dr George Grant of Newcastle University described formularies for non-hospital doctors; and Dr Joe Collier of St George's Hospital (London) commented on hospital formularies.

Other speakers and participants at the meeting included Charles Medawar, Professor Peter Schönhofer, Dr Axel Granitza, Dr Andrew Herxheimer, and Burkhard Sträter.

SCRIP, No. 1258, Nov. 18th, 1987

Who is Who?

Authors of the texts published in this reader

(in order of speeches)

Hermann Schulte-Sasse has been a member of the BUKO Pharma-Campaign for many years. He is a doctor specialized in internal medicine and spent several years in Ecuador. Today, he works for the Instite of Clinical Pharmacology in Bremen, FRG.

Dr. Mira Shiva is a doctor with the Voluntary Health Association of India, an umbrella organization of more than 3,000 indepen-det health projects, and a co-founder of the All India Drug Action Network.

Charles Medewar is a journalist who has been active in the British consumer movement for 15 years and who is a member of the independent information service "Social Audit".

Burkhard Sträter is a lawyer in Aachen, FRG.

George Grant is a (retired) general practitioner who teaches at the University of Newcastle, UK, and who developed a Standard Treatment Scheme in collaboration with some other doctors.

Joe Collier is Senior Lecturer and Honorary Consultant in Clinical Pharmacology at St. George's Hospital Medical School, London SW 17, UK.

Dr. Gerd Glaeske works for the Pharmacological Advisory Service of the Local Health Insurance Fund (AOK), Mettmann, FRG.

Jane Moffat, former member of Zimbabwe's National Drugs & Therapeutics Policy Committee. Currently employed by Brighton Health Authority at the Royal Sussex Country Hospital, Brighton, England. Unfortunately, she was not able to take part in the conference because of bad weather (flight) conditions. We should like to thank her for allowing us to publish the manuscript of her planned speech in this reader.

Dr. Gaut Gadeholt is a lecturer at the University of Oslo, Department of Pharmacotherapeutics, Norway.

Dr. Zaffrulah Chowdurhy is a surgeon and the co-founder of Gonoshastaya Kendra, a peoples health centre in Bangladesh.

Günter Lewandowski is employed by Ciba Geigy, Switzerland.

Dr. K. Balasubramaniam is Pharmaceutical Adviser of the International Organization of Consumers Unions (IOCU).

Ingrid Schubert is a former staff member of the Patientenstelle, Munich, FRG.

Prof. Borchert is a lawyer and a member of the Arbeitsgemeinschaft für Verbraucher (Working Group of Consumers), FRG.

Dr. Gunter Hildisch is a specialist in internal medicine working in Bremen, FRG.

Dr. Marc Bouniton is a doctor and a member of the project ARCHIMEDE in Belgium.

Prof. Georges Peters is a professor at the Institute of Pharmacology at the University of Lausanne, Switzerland.

Dr. Axel Granitza is a lawyer employed by Schering AG, FRG.

Apart from the above-mentioned authors of the texts the following persons contributed to the workshops:

Gert Monheim, WDR broadcasting station, FRG; Maria Müßeler, patient, FRG; Dr. Wolfgang Becker-Brüser, arznei-telegramm, Berlin, FRG; Luc Blondeel, Projekt Farmaka, Belgium; Dr. Andrew Herxheimer, Clinical Pharmacologist, London, UK; Prof. Peter Schönhofer, professor of clinical pharmacology, Bremen, FRG; Dr. Wilhelm Schräder, IGES, FRG; David Lee, Huddinge Hospital, Sweden; Prof. Reich, Centre for European Legal Policy (ZERP), Bremen, FRG.

On the 16-18th October, 1987 240 people took part in the international Conference on "Fewer Drugs – Better Therapy. Learning from the Third World?" held in Bielefeld, West Germany.

The most important result of this Conference: A scientifically justified selection of drugs is therapeutically useful and feasible, and it serves patients as well as doctors.

With this documentation the Pharma-Campaign of the Federal Congress of Development Action Groups (BUKO) presents contributions to, and results of the Conference. The documentations contains:

Speeches * Contributions of the Workshops * Results of the Workshops Evaluation of the Conference * Press Commentaries.

BUKO Pharma-Campaign

The Federal Congress of Development Action Groups (BUKO) is a network of more than 250 Solidarity Groups in the Federal Republic of Germany. In 1980 BUKO started a campaign against the global malpractice in drug marketing by the multinational pharmaceutical companies. BUKO is a co-founder of Health Action International (HAI). HAI is an informal cooperating network of some fifty consumer, development action and other public interest groups worldwide.

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